

Programmatic Environmental Assessment for Marketing Orders for Native Trading Associates “Native Full Flavor 100's Hard Pack (2016), Native Full Flavor 100's Soft (2016), Native Full Flavor King Hard Pack (2016), Native Full Flavor King Soft (2016), Native Menthol 100's Hard Pack (2016), Native Menthol 100's Soft (2016), Native Menthol King Hard Pack (2016), and Native Menthol King Soft (2016)”

Prepared by Center for Tobacco Products

U.S. Food and Drug Administration

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This programmatic environmental assessment (PEA) is for the marketing orders for eight combusted filtered cigarette products manufactured by Native Trading Associates. Information presented in the PEA is based on the submissions referenced in Section 4.3.2, unless noted or referenced otherwise. This PEA 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

Native Trading Associates

2. Address

Point of contact:
Troutman Sanders LLP
1001 Haxall Point
Richmond, VA 23219

3. Manufacturer

Native Trading Associates
442 Frogtown Road
Hogansburg, NY 13655

4. Description of Proposed Actions

These proposed actions are for the Food & Drug Administration (FDA) to issue marketing orders under the provisions of sections 910 and 905(j) of the FD&C Act for the introduction of eight combusted filtered cigarette products into interstate commercial distribution in the United States.

The authorizations are based on the finding that these new products are substantially equivalent to the corresponding predicate products that were on the market as of February 15, 2007. The applicant claimed that the new products differ from the corresponding predicate products in changes to the cigarette paper and plug wrap paper. For some products, there are additional changes in the filter (Confidential Appendix 1).

The predicate products are not currently marketed in the United States, and the applicant stated they intend to market only the new products after receiving marketing orders for them. The applicant provided marketing projections for the first and fifth years after marketing is authorized (Confidential Appendix 2).

4.1 Requested Action

Orders finding the tobacco products named in the title of this PEA are substantially equivalent to the corresponding predicate products.

4.2 Need for Action

Native Trading Associates wishes to introduce the new tobacco products as described into interstate commerce for commercial distribution in the United States. The applicant claims that the new products and corresponding predicate products have different characteristics but that the new products do not raise different questions of public health (sec 910(a)(3)(A)(ii) of the FD&C Act). After considering the substantial equivalence (SE) reports (SE0013372, 13373, 13374, 13375, 13384, 13385, 13386, and 13387), the Agency shall issue orders under the provisions of sections 910 and 905(j) of the FD&C Act when finding the new products to be substantially equivalent to the corresponding predicate products.

4.3 Identification of the New Tobacco Products that are the Subject of the Proposed Actions

4.3.1 Type of Tobacco Products

Combusted filtered cigarettes

4.3.2 Product Names and Submission Tracking Numbers

The names of the new products are listed below, along with the submission tracking numbers (STNs), the names of the corresponding predicate products, and the STNs for additional submissions in support of these applications.

New Product		Predicate Product			Additional STNs
STN	Name	STN	Name	Determination Date	
SE0013372	Native Full Flavor 100's Hard Pack (2016)	GF1200350	Native Full Flavor 100's Hard Pack	11/1/2012	SE0013580 SE0013723 SE0014084 SE0014307
SE0013373	Native Full Flavor 100's Soft (2016)	GF1200354	Native Full Flavor 100's Soft Pack	11/1/2012	
SE0013374	Native Full Flavor King Hard Pack (2016)	GF1200355	Native Full Flavor King Hard Pack	10/24/2012	
SE0013375	Native Full Flavor King Soft (2016)	GF1200356	Native Full Flavor King Soft Pack	11/15/2012	
SE0013384	Native Menthol 100's Hard Pack (2016)	GF1200365	Native Menthol 100's Hard Pack	11/15/2012	
SE0013385	Native Menthol 100's Soft (2016)	GF1200366	Native Menthol 100's Soft Pack	11/20/2012	
SE0013386	Native Menthol King Hard Pack (2016)	GF1200367	Native Menthol King Hard Pack	11/15/2012	
SE0013387	Native Menthol King Soft (2016)	GF1200368	Native Menthol King Soft Pack	11/20/2012	

4.3.3 Description of the Product Packages

The packaging for each of the finished new products is the same as that of the corresponding predicate products. The following table provides packaging information for the new and corresponding predicate products.

New Product		Predicate Product		Packaging Components for New and Predicate Products
STN	Name	STN	Name	
SE0013372	Native Full Flavor 100's Hard Pack (2016)	GF1200350	Native Full Flavor 100's Hard Pack	Hard pack Foil liner Pack overwrap Carton of 10 packs Shipping box of 60 cartons
SE0013373	Native Full Flavor 100's Soft (2016)	GF1200354	Native Full Flavor 100's Soft Pack	Soft pack Pack overwrap Carton of 10 packs Shipping box of 60 cartons
SE0013374	Native Full Flavor King Hard Pack (2016)	GF1200355	Native Full Flavor King Hard Pack	Hard pack Foil liner Pack overwrap Carton of 10 packs Shipping box of 60 cartons
SE0013375	Native Full Flavor King Soft (2016)	GF1200356	Native Full Flavor King Soft Pack	Soft pack Pack overwrap Carton of 10 packs Shipping box of 60 cartons
SE0013384	Native Menthol 100's Hard Pack (2016)	GF1200365	Native Menthol 100's Hard Pack	Hard pack Foil liner Pack overwrap Carton of 10 packs Shipping box of 60 cartons
SE0013385	Native Menthol 100's Soft (2016)	GF1200366	Native Menthol 100's Soft Pack	Soft pack Pack overwrap Carton of 10 packs Shipping box of 60 cartons
SE0013386	Native Menthol King Hard Pack (2016)	GF1200367	Native Menthol King Hard Pack	Hard pack Foil liner Pack overwrap Carton of 10 packs Shipping box of 60 cartons
SE0013387	Native Menthol King Soft (2016)	GF1200368	Native Menthol King Soft Pack	Soft pack Pack overwrap Carton of 10 packs Shipping box of 60 cartons

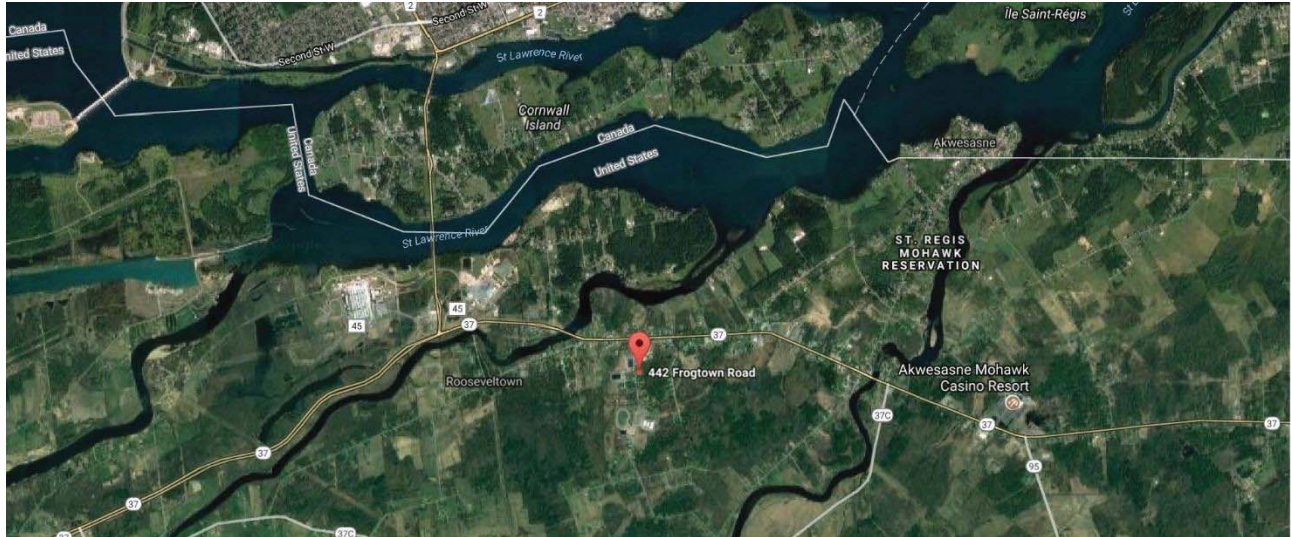
Details of the package component materials and weights of each packaging component for the new products are described in Confidential Appendix 3.

4.3.4 Location of Manufacturing

The products are manufactured at Native Trading Associates, located at 442 Frogtown Road, Hogsburg, NY 13655 (Figure 1). This location is within the St. Regis Mohawk Reservation. The reservation is adjacent to the St. Lawrence River and the U.S.-Canadian border in Franklin County, New York. The manufacturing facility is approximately one mile from the St. Lawrence River, less than a half mile from the Raquette River, and approximately 0.13 miles from a tributary to the Raquette River (Google, 2017) that is bounded by riverine wetlands. The facility itself is in a rural area with adjacent

commercial or industrial and shipping businesses to the north and west and undeveloped land with tree cover to the east and south. There are three isolated forested/shrub wetlands in the wooded area, each 0.10 to 0.15 miles from the facility (U.S. Environmental Protection Agency, 2017a).

Figure 1. Location of the Cigarette Product Manufacturing Facility



4.3.5 Location of Use

Native Trading Associates intends to distribute and sell the new tobacco products in the United States.

4.3.6 Location of Disposal

Once used, the new tobacco products will be disposed of as municipal solid waste (MSW) or litter, in the same manner as the predicate products and any other combusted filtered cigarette products. Discarded packaging materials will enter the recycling stream, be transported to MSW landfills or incinerators, or discarded as litter. The Agency anticipates the geographic distribution of waste from disposal after use will correspond to the geographic patterns of cigarette product use.

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

The applicant claimed that the new products differ from the corresponding predicate products in changes to the cigarette paper and plug wrap paper. For some products, there are additional changes in the filter (Confidential Appendix 1).

5. Potential Environmental Impacts Due to the Proposed Actions

5.1 Potential Environmental Impacts Due to Manufacturing the New Products

According to the SE Reports, the applicant purchases tobacco and standard components from established reputable suppliers in the tobacco industry and assembles the components to produce finished cigarettes at the Hogsburg facility.

The applicant provided information in the SE Reports related to environmental impacts from manufacturing, with the relevant points summarized as follows:

- The manufacturing process produces no unique emission circumstances that are not addressed by existing federal, tribal, and state laws and regulations, including occupational requirements.
- The manufacture of the new products does not threaten a violation of applicable environmental laws.
- No air pollution control is utilized at the facility.
- Solid waste is generated during the manufacturing process and is disposed of by a commercial trash company.
- The facility does not generate industrial waste water.
- The manufacture of the new products does not threaten any endangered species or critical habitat.

There is no entry for the facility in the U.S. Environmental Protection Agency's Enforcement and Compliance History Online database.

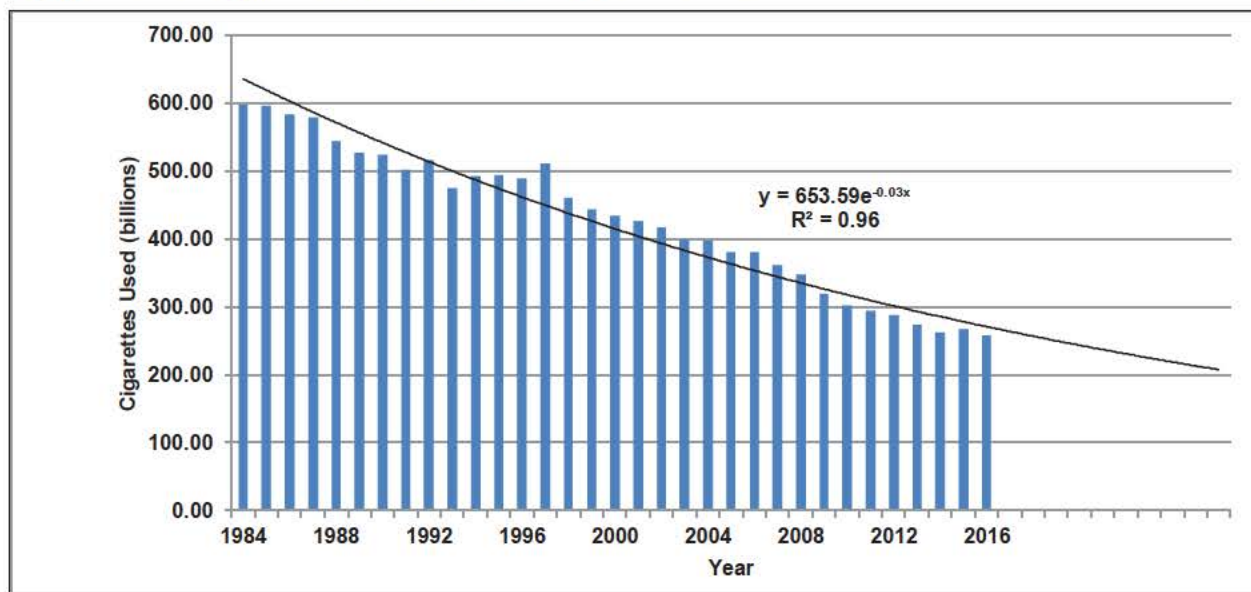
The Agency anticipates the environmental releases to the air and disposed of in the solid waste stream generated by manufacturing the new cigarette products would occur in the same manner as the releases and waste generated from any other products manufactured in the same facility and in a similar manner to other cigarette products manufactured in the United States.

The applicant stated that these products would replace similar products that are currently being marketed. This statement indicates that no additional capacity would be required for manufacturing or disposing of manufacturing waste and that manufacturing would not have any significant impact on greenhouse gas (GHG) emissions. The latter conclusion is consistent with the Agency's estimated GHG emissions from energy used in manufacturing the new products, based on energy consumption data provided by the applicant for this manufacturing facility (Confidential Appendix 4). Therefore, no effects from increased GHG emissions are anticipated from the proposed actions.

5.2 Potential Environmental Impacts Due to Use of the New Products

According to the U.S. Alcohol and Tobacco Tax and Trade Bureau's *Tobacco Statistical Release Reports*, the use of cigarettes in the United States decreased from 599 billion cigarettes in 1984 to 257 billion cigarettes in 2016 (Figure 2) (U.S. Alcohol and Tobacco Tax and Trade Bureau, 2017).

Figure 2. Use of Cigarettes in the United States in 1984–2016



The Agency analyzed the historical use data for 1984–2016 to forecast the future use of cigarettes in the United States. This was achieved by applying one best-fit power trend line with the R^2 value of 0.96. Using the equation displayed in Figure 2, the number of cigarettes estimated to be used in the United States is 236 billion in 2017 and 209 billion in 2021.

When using cigarettes, the users inhale the mainstream smoke and release tobacco smoke to the environment, referred to as secondhand smoke. There is no safe level of exposure to secondhand smoke (U.S. Department of Health and Human Services, 2006a) (U.S. Department of Health and Human Services, 2006b). Even low levels of secondhand smoke can harm children and adults in many ways, including the following:

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30 percent (HHS 2006a, 2006b).
- Exposure to secondhand smoke increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth, and it can cause coughing, wheezing, phlegm, and breathlessness (HHS 2006a, 2006b).
- Secondhand smoke causes more than 40,000 deaths a year (U.S. Department of Health and Human Services, 2014).

The predicate products are no longer marketed in the United States because they contained non-fire standard compliant paper, which is prohibited by laws in all 50 states. Therefore, the applicant intends to market only the new products after receiving marketing orders for them. Because the new products are expected to compete with other combusted filtered cigarette products on the market, and represent a small fraction of the total cigarette market in the United States (Confidential Appendix 5), the Agency anticipates minimal or no net increase in the use of all cigarettes. Thus, the Agency also does not anticipate more substances to be released into the environment from use of the new cigarette products relative to the substances released by other cigarette products already on the market.

The Agency does not anticipate new substances to be released into the environment as a result of use of the new cigarette products, relative to the substances released by use of cigarettes already on the market. The amount of carbon dioxide generated during combustion that contributes to GHG emissions is miniscule (Confidential Appendix 6) and, because the new products will compete with other currently marketed combusted cigarette products, no net addition to GHG emissions is anticipated.

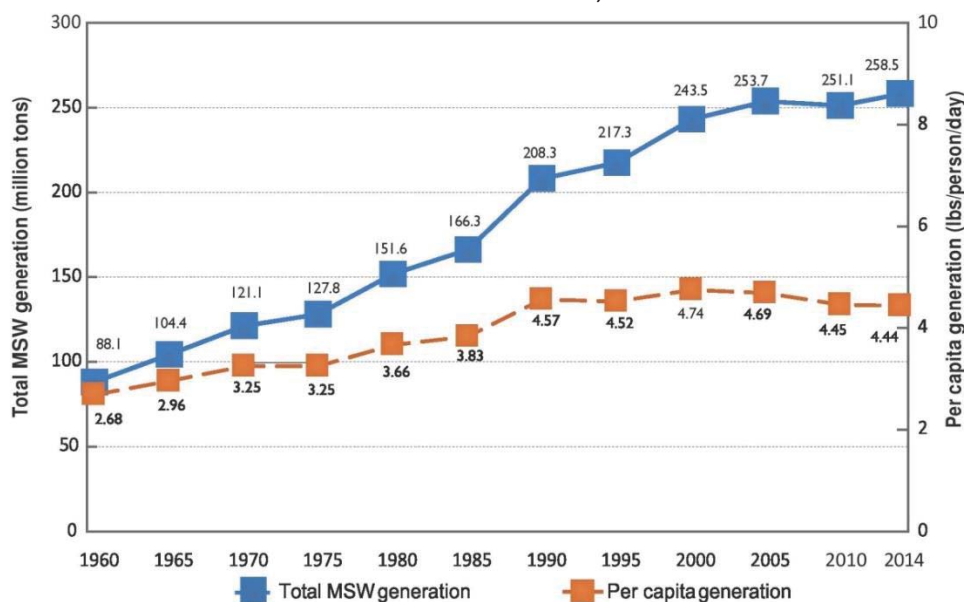
5.3 Potential Environmental Impacts Due to Disposal of the New Products

5.3.1 Disposal of Packaging Material

After using the new products, the users may recycle the packaging material or dispose of it as MSW or litter. Packaging disposal contributes to using landfill capacity.

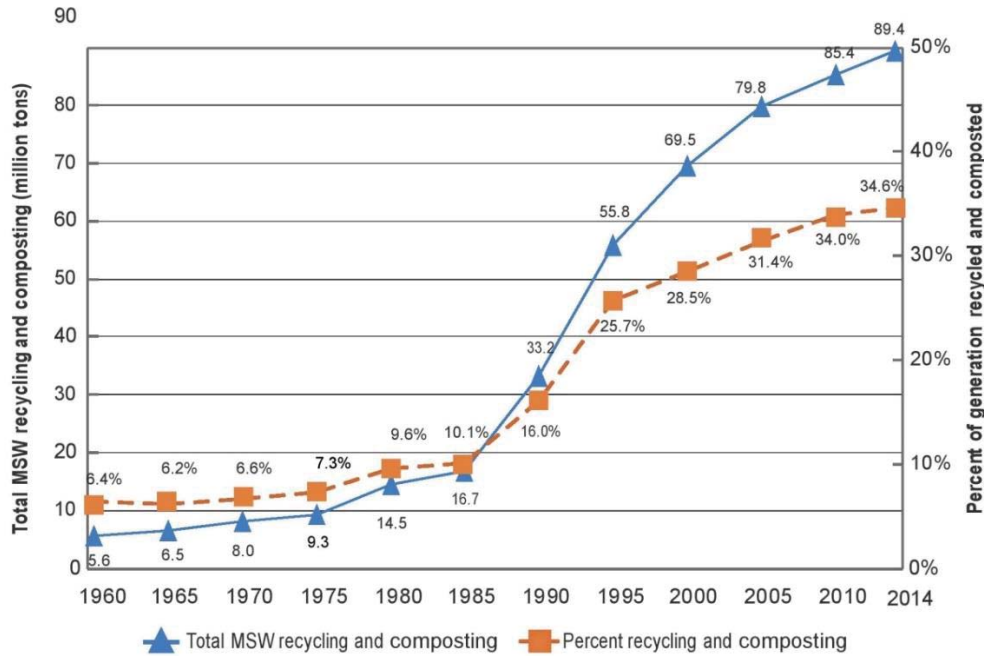
Following use, the packaging materials either would enter the recycling stream or be disposed of as MSW or litter. In 2014, approximately 258.46 million tons (234.47 metric tons) of trash was generated in the United States, and approximately 89.4 million tons (81.1 million metric tons) of this material was recycled and composted, equivalent to a 34.6% recycling rate (Figures 3 and 4). Paper and paperboard account for 68.61 million tons (62.24 million metric tons) (26.5%) of the total MSW generated in 2014. Plastics account for 33.25 million tons (30.16 metric tons) (12.9%) of total MSW generated in 2014. Containers and packaging comprised the largest portion of total MSW generated at 76.67 million tons (69.55 million metric tons) (29.7%), of which 39.13 million tons (35.50 million metric tons) was made of paper and paperboard. Of the total paper and paperboard MSW, 44.4 million tons (40.3 million metric tons) (64.7%) was recycled, 19.47 million tons (17.66 million metric tons) (28.4%) was disposed of in landfills, and 4.74 million tons (4.30 million metric tons) (6.9%) was combusted with energy recovery. On average, 4.4 pounds (2.0 kilograms) of waste was generated per person per day in the United States, of which 2.1 pounds (0.95 kilograms) was recycled, composted, or combusted for energy recovery (U.S. Environmental Protection Agency, 2016a).

Figure 3. MSW Generation Rates in the United States, 1960 – 2014



Source: (U.S. Environmental Protection Agency, 2016b).

Figure 4. MSW Recycling Rates in the United States, 1960 – 2014



Source: (U.S. Environmental Protection Agency, 2016b).

The Agency used the projected market volumes for the first and fifth years of marketing to estimate the waste from disposal of packaging, accounting for recycling of packaging waste as part of overall U.S. recycling of MSW. The estimated waste from packaging disposal after use would be miniscule compared to the total MSW forecasted to be discarded in the United States (Confidential Appendix 7).

Because the new combusted filtered cigarette products will compete with other similar combusted filtered cigarette products on the market and the estimates described above and detailed in Confidential Appendix 7 indicate a negligible contribution to U.S. MSW, construction of new solid waste landfills or incinerators is not anticipated due to disposal of packaging material under the proposed actions.

5.3.2 Discarding Used Products

Cigarette butt¹ waste may have an end-of-life-cycle scenario as either managed or unmanaged waste.

Managed waste is handled by an organized solid waste collection and management system. For the managed waste, 80.4% by weight enters landfills, and the remaining 19.6% by weight is incinerated for energy recovery (U.S. Environmental Protection Agency, 2016a). The Agency used the projected market volumes for the first and fifth years of marketing to estimate the waste from discarding used products (cigarette butts). The estimated waste from cigarette butt disposal as MSW would be miniscule compared to the total MSW forecasted to be discarded in the United States (Confidential Appendix 7). Because the new combusted filtered cigarette products will compete with other similar combusted filtered cigarette products on the market and the estimates described above and detailed in Confidential

¹ "Cigarette butt" is defined in this PEA as the filter and cigarette rolling paper containing remainder tobacco that is disposed of following use.

Appendix 7 indicate a negligible contribution to U.S. MSW, construction of new solid waste landfills or incinerators is not anticipated due to disposal of used products under the proposed actions.

Unmanaged waste consists of littered cigarette butts. The environmental effects of cigarette butt litter were summarized as follows (Novotny, et al., 2015):

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.

Introducing the new products into the U.S. market is not expected to increase the nationwide use of combusted filtered cigarettes; instead, they would compete for market share with existing products. Thus, authorizing the new products is not expected to affect the overall level of cigarette butt litter in the United States, but may displace the level of litter from other cigarette products.

5.3.3 Air Emissions from Disposal

Landfill disposal or incineration of the used products and packaging materials will produce GHGs.

Methane is a potent GHG that has a global warming potential 28–36 times greater than carbon dioxide and persists in the atmosphere for about 12 years. Landfills are the third largest source of human-related methane emissions in the United States, accounting for approximately 15.4% of these emissions in 2015 (U.S. Environmental Protection Agency, 2017b). Estimated GHG emissions from disposal of the used products and packaging associated with the new products are miniscule (Confidential Appendix 6).

6. Fate of Materials Released into the Environment due to the Proposed Actions

The Agency does not anticipate that the proposed actions will lead to the release of new chemicals into the environment because the new products would be manufactured, used, and disposed of in the same way as other combusted filtered cigarette products. Therefore, the fate of any materials released is anticipated to be the same as any materials from other combusted filtered cigarette products manufactured in the same or similar facilities that are used and discarded in the same manner.

7. Environmental Effects of New Materials Released into the Environment due to the Proposed Actions

The applicant stated that the manufacturing process produces no unique emission circumstances that are not addressed by existing federal, tribal, and state laws and regulations, including occupational requirements. Further, the applicant stated that manufacturing the new products does not threaten a violation of applicable environmental laws.

As discussed in sections 5.1 through 5.3, the amount of materials anticipated to enter the environment due to the manufacturing, use, and disposal of the new products are small fractions when compared to

that of all cigarette products projected to be manufactured and used in the United States. No new substances or new types of emissions are expected to be released, and therefore no new environmental controls are needed. No new environmental effects are anticipated due to the new products.

8. Use of Resources and Energy

The applicant stated that the manufacture of the new products does not threaten any endangered species or critical habitat. Therefore, the Agency did not identify any concerns related to Endangered Species Act-listed species or critical habitat, or species protected under the Convention on International Trade in Endangered Species of Wild Fauna and Flora.

The applicant provided quantitative information on energy used to manufacture the new products and the fraction of total production for the new products at the manufacturing facility. No significant impacts from emissions of GHGs were indicated based on these data (Confidential Appendix 6).

9. Mitigation

The Agency did not identify significant adverse environmental effects for the new products. Therefore, no mitigation measures were developed.

10. Alternatives to the Proposed Actions

Alternative A (No-action alternative). The no-action alternative is to not authorize the marketing of the new tobacco products in the United States. The environmental impact of the no-action alternative would not change the existing condition of the manufacturing, use, and disposal following use of combusted filtered cigarette products, as many other similar cigarette products will continue to be marketed.

Alternative B (Proposed actions). There is no significant environmental effect due to the proposed actions of authorizing the new products and the associated manufacturing, use, and disposal following use of the products.

11. List of Preparers

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

Preparers:

Christine M. Modovsky, M.S., Center for Tobacco Products (product-specific analyses)

Education: M.S. in Environmental Science

Experience: 29 years in environmental compliance and analysis

Expertise: NEPA analysis, regulatory compliance, evaluation of environmental health and ecological effects

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Education: Ph.D. in Plant Molecular Biology and Virology

Experience: 23 years in various scientific activities
Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA implementation

Catherine W. McCollum, Ph.D., Center for Tobacco Products (impact analysis framework)

Education: Ph.D. in Biochemistry and Cell Biology

Experience: 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 PhD in Biochemistry

Experience: 9 years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

12. List of Agencies and Persons Consulted

Not applicable.

13. Confidential Appendix List

Confidential Appendix 1: Comparison of the New and Corresponding Predicate Products

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

Confidential Appendix 3: Package Materials and Mass for New Products

Confidential Appendix 4: Energy Consumption at Manufacturing Facility

Confidential Appendix 5: Comparison of the U.S. Market Volumes for the New Products with Total Manufactured Cigarette Products

Confidential Appendix 6: Greenhouse Gas Emissions from Use and Disposal of the Products

Confidential Appendix 7: Projected Product and Packaging Waste from Disposal as Municipal Solid Waste after Use

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CONFIDENTIAL APPENDIX 1: Comparison of the New and Corresponding Predicate Products

The applicant claimed that the new products differ from the corresponding predicate products in changes to the cigarette paper and plug wrap paper. For some products, there are additional changes in the filter.

The applicant provided the product material details for the new and predicate products as listed in the following table. The information listed here is taken directly from the SE Reports and amendments.

STN	New Product	Predicate Product	Changes in Composition as Compared to the Corresponding Predicate Product				
			Filter Plasticizer	Cigarette Paper		Plug Wrap Paper – Ingredient Changes	Tipping Paper – Ingredient Changes
				FSC-Compliant	Ingredient Changes		
SE0013372	Native Full Flavor 100's Hard Pack (2016)	Native Full Flavor 100's Hard Pack	No change.	New products are FSC-compliant. Predicate products did not have FSC cigarette paper.	(b) (4) : decreased. (b) (4) : new ingredient. (b) (4) : increased, different chemical species. (b) (4) : slightly increased. (b) (4) : increased. (b) (4) : eliminated.	(b) (4) : decreased. (b) (4) : increased. (b) (4) : eliminated. Four processing aids added. Two processing aids eliminated.	(b) (4) : slightly increased. (b) (4) : slightly decreased. Coloring and binding agents: slightly increased. Sizing agent: replaced Two processing aids eliminated and two increased. Changes to amounts of pigments, solvents, and waxes for printing.
SE0013373	Native Full Flavor 100's Soft (2016)	Native Full Flavor 100's Soft Pack					
SE0013374	Native Full Flavor King Hard Pack (2016)	Native Full Flavor King Hard Pack	Slightly decreased.				
SE0013375	Native Full Flavor King Soft (2016)	Native Full Flavor King Soft Pack					
SE0013384	Native Menthol 100's Hard Pack (2016)	Native Menthol 100's Hard Pack	No change.				
SE0013385	Native Menthol 100's Soft (2016)	Native Menthol 100's Soft Pack					
SE0013386	Native Menthol King Hard Pack (2016)	Native Menthol King Hard Pack	Slightly decreased.				
SE0013387	Native Menthol King Soft (2016)	Native Menthol King Soft Pack					

CONFIDENTIAL APPENDIX 2: The First- and Fifth-Year Market Volume Projections of the New Products

The predicate products are no longer on the market. The applicant stated that if these products receive a marketing order, they will replace similar products that are currently being marketed, and the market volume projection of the new products is the same as for the current products they would replace (SE0014307).

STN	Product	Measure	Market Volume (cigarettes)	
			First Year	Fifth Year
SE0013372	Native Full Flavor 100's Hard Pack (2016)	Cigarettes	(b) (4)	
SE0013373	Native Full Flavor 100's Soft (2016)	Cigarettes		
SE0013374	Native Full Flavor King Hard Pack (2016)	Cigarettes		
SE0013375	Native Full Flavor King Soft (2016)	Cigarettes		
SE0013384	Native Menthol 100's Hard Pack (2016)	Cigarettes		
SE0013385	Native Menthol 100's Soft (2016)	Cigarettes		
SE0013386	Native Menthol King Hard Pack (2016)	Cigarettes		
SE0013387	Native Menthol King Soft (2016)	Cigarettes		
TOTAL				

CONFIDENTIAL APPENDIX 3: Package Materials and Mass for New Products

STN	Product	Packaging Component	Material	Weight (grams)
SE0013372	Native Full Flavor 100's Hard Pack (2016)	Hard pack	Cardboard	5.5
		Pack liner	Aluminum foil	1.0
		Pack overwrap	Polypropylene	0.5
		Carton of 10 packs	Cardboard	22.8
		Shipping box of 60 cartons	Cardboard	958.0
SE0013373	Native Full Flavor 100's Soft (2016)	Soft pack	Paperboard – Grade C1S	1.6
		Pack liner	Aluminum foil	1.2
		Pack overwrap	Polypropylene	0.5
		Carton of 10 packs	Cardboard	21.9
		Shipping box of 60 cartons	Cardboard	956.5
SE0013374	Native Full Flavor King Hard Pack (2016)	Hard pack	Cardboard	4.6
		Pack liner	Aluminum foil	0.9
		Pack overwrap	Polypropylene	0.4
		Carton of 10 packs	Cardboard	20.2
		Shipping box of 60 cartons	Cardboard	930.5
SE0013375	Native Full Flavor King Soft (2016)	Soft pack	Paperboard – Grade C1S	1.4
		Pack liner	Aluminum foil	1.1
		Pack overwrap	Polypropylene	0.4
		Carton of 10 packs	Cardboard	19.6
		Shipping box of 60 cartons	Cardboard	874.5
SE0013384	Native Menthol 100's Hard Pack (2016)	Hard pack	Cardboard	5.5
		Pack liner	Aluminum foil	1.0
		Pack overwrap	Polypropylene	0.5
		Carton of 10 packs	Cardboard	22.8
		Shipping box of 60 cartons	Cardboard	958.0
SE0013385	Native Menthol 100's Soft (2016)	Soft pack	Paperboard – Grade C1S	1.6
		Pack liner	Aluminum foil	1.2
		Pack overwrap	Polypropylene	0.5
		Carton of 10 packs	Cardboard	21.9
		Shipping box of 60 cartons	Cardboard	956.5
SE0013386	Native Menthol King Hard Pack (2016)	Hard pack	Cardboard	4.6
		Pack liner	Aluminum foil	0.9
		Pack overwrap	Polypropylene	0.4
		Carton of 10 packs	Cardboard	20.2
		Shipping box of 60 cartons	Cardboard	930.5
SE0013387	Native Menthol King Soft (2016)	Soft pack	Paperboard – Grade C1S	1.4
		Pack liner	Aluminum foil	1.1
		Pack overwrap	Polypropylene	0.4
		Carton of 10 packs	Cardboard	19.6
		Shipping box of 60 cartons	Cardboard	874.5

CONFIDENTIAL APPENDIX 4: Energy Consumption at Manufacturing Facility

The applicant stated that the amount of energy expected to be used producing the eight new products at Native Trading Associate's manufacturing location is approximately (b) (4) kilowatt-hours of electricity. This is approximately (b) (4) of the total energy used by the facility in manufacturing tobacco products. The applicant estimated the energy use for each product, as shown in the table below. The applicant stated that the energy source is electricity provided by the National Grid Electric Company and that if these products receive a marketing order, they would replace similar products that are currently being marketed, so the facility's energy use would not change (SE0014307).

STN	New Product	Electricity Used (kilowatt-hour/year) ^a
SE0013372	Native Full Flavor 100's Hard Pack (2016)	(b) (4)
SE0013373	Native Full Flavor 100's Soft (2016)	(b) (4)
SE0013374	Native Full Flavor King Hard Pack (2016)	(b) (4)
SE0013375	Native Full Flavor King Soft (2016)	(b) (4)
SE0013384	Native Menthol 100's Hard Pack (2016)	(b) (4)
SE0013385	Native Menthol 100's Soft (2016)	(b) (4)
SE0013386	Native Menthol King Hard Pack (2016)	(b) (4)
SE0013387	Native Menthol King Soft (2016)	(b) (4)
TOTAL		(b) (4)

^a The applicant stated that the electricity used would stay the same after the new products are authorized, since marketing these products would lead to decreased production of other similar products manufactured at the same facility, resulting in no facility-wide change in total energy use. Thus, these rates are assumed to be reasonable indicators of energy use for both the first and fifth years of marketing.

The 2014 (most recent available) energy generation source mix for this subregion was 30.6% nuclear power, 30.4% hydropower, 25.9% natural gas, 6.8% non-hydropower renewable sources, 5.5% coal, and 0.6% oil (U.S. Environmental Protection Agency, 2017c).

CONFIDENTIAL APPENDIX 5: Comparison of the U.S. Market Volumes for the New Products with Total Manufactured Cigarette Products

The first- and fifth-year U.S. market volume projections (Confidential Appendix 2) for the new products were compared to the total projected manufactured cigarette market volumes (Figure 2 in section 5.2) in the United States.

STN	Name	Market Volume			
		First Year		Fifth Year	
		Cigarettes	% Cigarette Market ^a	Cigarettes	% Cigarette Market ^a
SE0013372	Native Full Flavor 100's Hard Pack (2016)	(b) (4)			
SE0013373	Native Full Flavor 100's Soft (2016)				
SE0013374	Native Full Flavor King Hard Pack (2016)				
SE0013375	Native Full Flavor King Soft (2016)				
SE0013384	Native Menthol 100's Hard Pack (2016)				
SE0013385	Native Menthol 100's Soft (2016)				
SE0013386	Native Menthol King Hard Pack (2016)				
SE0013387	Native Menthol King Soft (2016)				
	TOTAL				

^a Projected first year (2017) U.S. cigarette market:

(b) (4)

cigarettes

Projected fifth year (2021) U.S. cigarette market:

(b) (4)

cigarettes

CONFIDENTIAL APPENDIX 6: Greenhouse Gas Emissions from Use and Disposal of the Products

GHG Emissions from Manufacturing Products

The amount of carbon dioxide-equivalent (CO₂-eq) gases emitted from manufacturing the new products was estimated based on the projected energy use at the manufacturing facility (Confidential Appendix 4). The energy use in kilowatt-hours (kWh) was multiplied by a factor of 379.206 pounds CO₂-eq per megawatt-hour (MWh) of electricity consumed, as follows:

$$CO_2\text{-eq (metric tons)} = \text{energy use (kWh)} \times \frac{0.001 \text{ MWh}}{\text{kWh}} \times \frac{379.206 \text{ lb } CO_2\text{-eq}}{\text{MWh}} \times \frac{\text{metric ton}}{2204.62 \text{ lb}}$$

The factor for the amount of CO₂-eq emitted by the mix of electricity generation sources specific to the "NYUP" subregion of the United States was identified using EPA's eGRID data (U.S. Environmental Protection Agency, 2017d). The total GHG emissions from manufacturing were estimated to be (b) (4) metric tons of CO₂-eq for the first year and fifth year, respectively. In each case, this is a negligible fraction (<0.0000001%) of the 6.87 billion metric tons of CO₂-eq estimated to have been generated in the United States in 2014.

STN	Name	Metric Tons of CO ₂ -eq	
		First Year	Fifth Year
SE0013372	Native Full Flavor 100's Hard Pack (2016)	(b) (4)	(b) (4)
SE0013373	Native Full Flavor 100's Soft (2016)	(b) (4)	(b) (4)
SE0013374	Native Full Flavor King Hard Pack (2016)	(b) (4)	(b) (4)
SE0013375	Native Full Flavor King Soft (2016)	(b) (4)	(b) (4)
SE0013384	Native Menthol 100's Hard Pack (2016)	(b) (4)	(b) (4)
SE0013385	Native Menthol 100's Soft (2016)	(b) (4)	(b) (4)
SE0013386	Native Menthol King Hard Pack (2016)	(b) (4)	(b) (4)
SE0013387	Native Menthol King Soft (2016)	(b) (4)	(b) (4)
Total, new products:		(b) (4)	(b) (4)
Total U.S. generation of CO ₂ -eq (2014):		6,870,000,000	
New products as a % of total U.S. generation of CO ₂ -eq:		(b) (4)	(b) (4)

GHG Emissions from Use of Products

The amount of CO₂-eq emitted from the use of cigarettes has been estimated to be 45–65 mg per cigarette (Geiss & Dimitrios, 2007). The total GHG emissions were estimated to be (b) (4) metric tons of CO₂-eq for the first year and fifth year, respectively. In each case, this is a negligible fraction (<0.0000008%) of the 6.87 billion metric tons of CO₂-eq estimated to have been generated in the United States in 2014.

STN	Name	Metric Tons of CO ₂ -eq	
		First Year	Fifth Year
SE0013372	Native Full Flavor 100's Hard Pack (2016)	(b) (4)	(b) (4)
SE0013373	Native Full Flavor 100's Soft (2016)	(b) (4)	(b) (4)
SE0013374	Native Full Flavor King Hard Pack (2016)	(b) (4)	(b) (4)
SE0013375	Native Full Flavor King Soft (2016)	(b) (4)	(b) (4)
SE0013384	Native Menthol 100's Hard Pack (2016)	(b) (4)	(b) (4)
SE0013385	Native Menthol 100's Soft (2016)	(b) (4)	(b) (4)
SE0013386	Native Menthol King Hard Pack (2016)	(b) (4)	(b) (4)
SE0013387	Native Menthol King Soft (2016)	(b) (4)	(b) (4)
Total, new products:		(b) (4)	(b) (4)
Total U.S. generation of CO₂-eq (2014):		6,870,000,000	
New products as a % of total U.S. generation of CO₂-eq:		(b) (4)	(b) (4)

GHG Emissions from Disposal of Products

GHG emissions from the product waste and packaging were calculated using the GHG emission rates from the Waste Reduction Model (WARM), v. 14 (U.S. Environmental Protection Agency, 2016c). WARM estimates GHG emissions across different material types commonly found in MSW. Taking into account the waste generated (Confidential Appendix 7), the rates for recycling, landfill disposal, and combustion with energy recovery of the various material types in the new products, the total amount of GHG emissions from product waste and packaging disposal was estimated to be (b) (4) metric tons of CO₂-eq for the first year and fifth year, respectively. In each case, this is a negligible fraction (<0.0000004% or less) of the 6.87 billion metric tons of CO₂-eq estimated to have been generated in the United States in 2014.

STN	Name	Metric Tons of CO ₂ -eq	
		First Year	Fifth Year
SE0013372	Native Full Flavor 100's Hard Pack (2016)	(b) (4)	
SE0013373	Native Full Flavor 100's Soft (2016)		
SE0013374	Native Full Flavor King Hard Pack (2016)		
SE0013375	Native Full Flavor King Soft (2016)		
SE0013384	Native Menthol 100's Hard Pack (2016)		
SE0013385	Native Menthol 100's Soft (2016)		
SE0013386	Native Menthol King Hard Pack (2016)		
SE0013387	Native Menthol King Soft (2016)		
Total, new products:			
Total U.S. generation of CO ₂ -eq (2014):		6,870,000,000	
New products as a % of total U.S. generation of CO ₂ -eq:		(b) (4)	

CONFIDENTIAL APPENDIX 7: Projected Product and Packaging Waste from Disposal as Municipal Solid Waste after Use

To analyze the environmental effects from used product (cigarette butts) and packaging disposed of as MSW in landfills or incinerators, the Agency estimated the weights of the non-recycled waste that would be generated from disposal after use of the products in the first and fifth years of marketing. Projected used product and packaging waste is the sum of the cigarette butt and the paper, cardboard, plastic, and mixed materials specific to the packaging for each product (Confidential Appendix 3), as follows:

$$\sum_{i=1}^8 A_i (\text{tons}) = \sum_{i=1}^8 (B_i + C_i + D_i + E_i)$$

$$B_i (\text{tons}) = F \times G_i (\text{ounces}) \times H_i (\text{cigarettes}) \times \frac{\text{pound}}{16 \text{ ounces}} \times \frac{\text{ton}}{2,000 \text{ pounds}}$$

$$C_i (\text{tons}) = H_i (\text{cigarettes}) \times \left[\frac{I_i (\text{grams})}{20 \text{ cigarettes}} + \frac{J_i (\text{grams})}{200 \text{ cigarettes}} + \frac{K_i (\text{grams})}{12,000 \text{ cigarettes}} \right] \times L \times \frac{\text{ton}}{907,184.74 \text{ grams}}$$

$$D_i (\text{tons}) = H_i (\text{cigarettes}) \times \frac{M_i (\text{grams})}{20 \text{ cigarettes}} \times N \times \frac{\text{ton}}{907,184.74 \text{ grams}}$$

$$E_i (\text{tons}) = H_i (\text{cigarettes}) \times \frac{O_i (\text{grams})}{20 \text{ cigarettes}} \times \frac{\text{ton}}{907,184.74 \text{ grams}}$$

$$G_i (\text{ounces}) = [P_i (\text{milligrams}) + Q_i (\text{milligrams}) + R_i (\text{milligrams})] \times \frac{\text{ounce}}{28,350 \text{ milligrams}}$$

$$H_i (\text{ounces}) = \frac{J (\text{millimeters})}{K_i (\text{millimeters})} \times \left(\frac{0.0325 \text{ ounces RYO tobacco}}{\text{cigarette-equivalent}} + \frac{L_i (\text{ounces})}{\text{cigarette-equivalent}} \right)$$

$$R_i (\text{milligrams}) = [(S_i + T_i) (\text{milligrams})] \times \frac{(U_i - V_i) (\text{millimeters})}{W_i (\text{millimeters})}$$

A_i = total cigarette butt and packaging waste generated by the new products (tons)

B_i = cigarette butts generated by the used products (tons)

C_i = cardboard and paper waste generated by the packaging for the new products (tons)

D_i = plastic waste generated by the packaging for the new products (tons)

E_i = mixed and other materials waste generated by the packaging for the new products (tons)

F = fraction of cigarette butts disposed of in MSW = 0.66 (34% are littered)

G_i = weight per cigarette butt (ounces)

H_i = market volume projection (cigarettes)

I_i = pack (grams)

J_i = carton (grams)

K_i = shipping box (grams)

L = fraction of cardboard paper waste not recycled = 1 - 0.647 = 0.353 (U.S. EPA 2016a)

M_i = polypropylene shrinkwrap (grams)

N = fraction of polypropylene not recycled = 1 - 0.008 = 0.992 (U.S. EPA 2016a)

O_i = foil pack liner (grams)

P_i = filter + plug wrap (milligrams)

Q_i = tipping paper (milligrams)

R_i = cigarette paper in cigarette butt + tobacco rod filler in cigarette butt (milligrams)

S_i = cigarette paper in cigarette (milligrams)
 T_i = tobacco rod filler in cigarette (milligrams)
 U_i = cigarette butt length (millimeters). For filtered cigarettes: the greatest of 23 mm, length of filter + 8 mm, or length of overwrap + 3 mm, from draft

2015 revisions to ISO 3308 intense smoking regimen (Section 7.2.1). For unfiltered cigarettes: 27 mm, from ISO 15592-3:2008(E).
 V_i = filter length (millimeters)
 W_i = cigarette rod length (millimeters)

The product packaging elements are disposed of as MSW or recycled, and the cigarette butts are disposed of as MSW or litter. The Agency estimated the amount of MSW that would be disposed of in landfills or incinerated, after accounting for portions of the paper and plastic packaging being recycled at rates of 64.7% for paper and cardboard products and 0.8% for polypropylene plastic products (U.S. Environmental Protection Agency, 2016a). The total estimated MSW generated from the new products is (b) (4) tons (b) (4) metric tons) in the first and fifth years of marketing, respectively. This is a negligible fraction (b) (4) of the 192,080,000 tons (174,250,000 metric tons) of total MSW generated and not recycled in the United States in 2014.

The following tables detail the parameters used in the calculations for MSW generation from the new products in the first and fifth years of marketing.

First Year	STN	Name	W	V	U	T	S	R	Q	P	O	N	M	L	K	J	I	H	G	F	E	D	C	B	A	
	SE0013372	Native Full Flavor 100's Hard Pack (2016)	75	25	33	978	56.7	110.368	26.93	151	0.050	0.992	0.025	0.353	958.0	22.8	5.5	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
	SE0013373	Native Full Flavor 100's Soft (2016)	75	25	33	978	56.7	110.368	26.93	151	0.060	0.992	0.025	0.353	956.5	21.9	1.6	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
	SE0013374	Native Full Flavor King Hard Pack (2016)	64	20	30	830	48.4	137.250	22.34	133	0.045	0.992	0.020	0.353	930.5	20.2	4.6	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
	SE0013375	Native Full Flavor King Soft (2016)	64	20	30	830	48.4	137.250	22.34	133	0.055	0.992	0.020	0.353	874.5	19.6	1.4	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
	SE0013384	Native Menthol 100's Hard Pack (2016)	75	25	33	978	56.7	110.368	26.93	151	0.050	0.992	0.025	0.353	958.0	22.8	5.5	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
	SE0013385	Native Menthol 100's Soft (2016)	75	25	33	978	56.7	110.368	26.93	151	0.060	0.992	0.025	0.353	956.5	21.9	1.6	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
	SE0013386	Native Menthol King Hard Pack (2016)	64	20	30	830	48.4	137.250	22.34	133	0.045	0.992	0.020	0.353	930.5	20.2	4.6	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
	SE0013387	Native Menthol King Soft (2016)	64	20	30	830	48.4	137.250	22.34	133	0.055	0.992	0.020	0.353	874.5	19.6	1.4	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)
																	Subtotal, MSW from disposal of new products after use (tons)						(b) (4)			
																	Total MSW disposed of (not recycled) in U.S. (2014) (tons)						192,080,000			
																	MSW from product disposal as a % of total MSW disposed of in U.S.						(b) (4)			

Fifth Year	STN	Name	W	V	U	T	S	R	Q	P	O	M	M	L	K	J	I	H	G	F	E	D	C	B	A
	SE0013372	Native Full Flavor 100's Hard Pack (2016)	75	25	33	978	56.7	110.368	26 93	151	0 050	0.992	0.025	0.353	958 0	22 8	6	(b) (4)							
	SE0013373	Native Full Flavor 100's Soft (2016)	75	25	33	978	56.7	110.368	26 93	151	0 060	0.992	0.020	0.353	956 5	21 9	2	(b) (4)							
	SE0013374	Native Full Flavor King Hard Pack (2016)	64	20	30	830	48.4	137.250	22 34	133	0 045	0.992	0.020	0.353	930 5	20 2	5	(b) (4)							
	SE0013375	Native Full Flavor King Soft (2016)	64	20	30	830	48.4	137.250	22 34	133	0 055	0.992	0.025	0.353	874 5	19.6	1	(b) (4)							
	SE0013384	Native Menthol 100's Hard Pack (2016)	75	25	33	978	56.7	110.368	26 93	151	0 050	0.992	0.025	0.353	958 0	22 8	6	(b) (4)							
	SE0013385	Native Menthol 100's Soft (2016)	75	25	33	978	56.7	110.368	26 93	151	0 060	0.992	0.020	0.353	956 5	21 9	2	(b) (4)							
	SE0013386	Native Menthol King Hard Pack (2016)	64	20	30	830	48.4	137.250	22 34	133	0 045	0.992	0.020	0.353	930 5	20 2	5	(b) (4)							
	SE0013387	Native Menthol King Soft (2016)	64	20	30	830	48.4	137.250	22 34	133	0 055	0.992	1.000	0.353	874 5	19.6	1	(b) (4)							
																	Subtotal, MSW from disposal of new products after use (tons)					(b) (4)			
																	Total MSW disposed of (not recycled) in U.S. (2014) (tons)					192,080,000			
																	MSW from product disposal as a % of total MSW disposed of in U.S.					(b) (4)			