

**Programmatic Environmental Assessment for Marketing
Orders for Three Loose Moist Snuff Products by
Swisher International, Inc.**

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

February 27, 2019

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1. Applicant and Manufacturer Information

Applicant Name:	Swisher International, Inc.
Applicant Address:	459 E. 16 th Street Jacksonville, FL 32206
Manufacturer Name:	Swisher International, Inc.
Product Manufacturing Address:	4000 Water Street Wheeling, WV 26003

2. Product Information

New Product Names, Submission Tracking Numbers (STN), and Predicate Product Names

New Product Name	New Product STN	Predicate Product Name
Kayak Fine Cut Natural	SE0011094	Kayak Fine Cut Natural
Kayak Long Cut Straight	SE0011095	Kayak Long Cut Straight
Kayak Long Cut Wintergreen	SE0011096	Kayak Long Cut Wintergreen

Product Identification

Product Category	Smokeless
Product Sub-Category	Loose Moist Snuff
Product Quantity Per Unit of Sale	14.4 oz. loose moist snuff per can, eight cans per shipping case
Product Package¹	Plastic can bottom with plastic lid and additional empty polypropylene can with polypropylene lid identical to the predicate product package for refills

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the U.S. Food and Drug Administration (FDA) to issue marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act after finding the new tobacco products substantially equivalent to the corresponding predicate products.

The applicant wishes to introduce three new tobacco products into interstate commerce for commercial distribution in the United States and submitted to the Agency three substantial equivalence (SE) reports to obtain marketing orders. The Agency shall issue marketing orders if, after considering the substantial equivalence (SE) report and any amendments submitted by the applicant, the new products are found substantially equivalent to the corresponding predicate products. The predicate products in SE0011094 and SE0011096 are provisional products, whereas the predicate product in SE0011095 is a grandfathered product commercially marketed in the United States as of February 15, 2007.

The new products differ from the corresponding predicate products in product quantity, packaging design (Appendix 1), and packaging ingredients (Confidential Appendix 1).

¹ See Confidential Appendix 1 for the packaging material of the new and corresponding predicate products.

4. Alternatives to the Proposed Actions

The no-action alternative is FDA does not issue marketing orders for the new tobacco products in the United States.

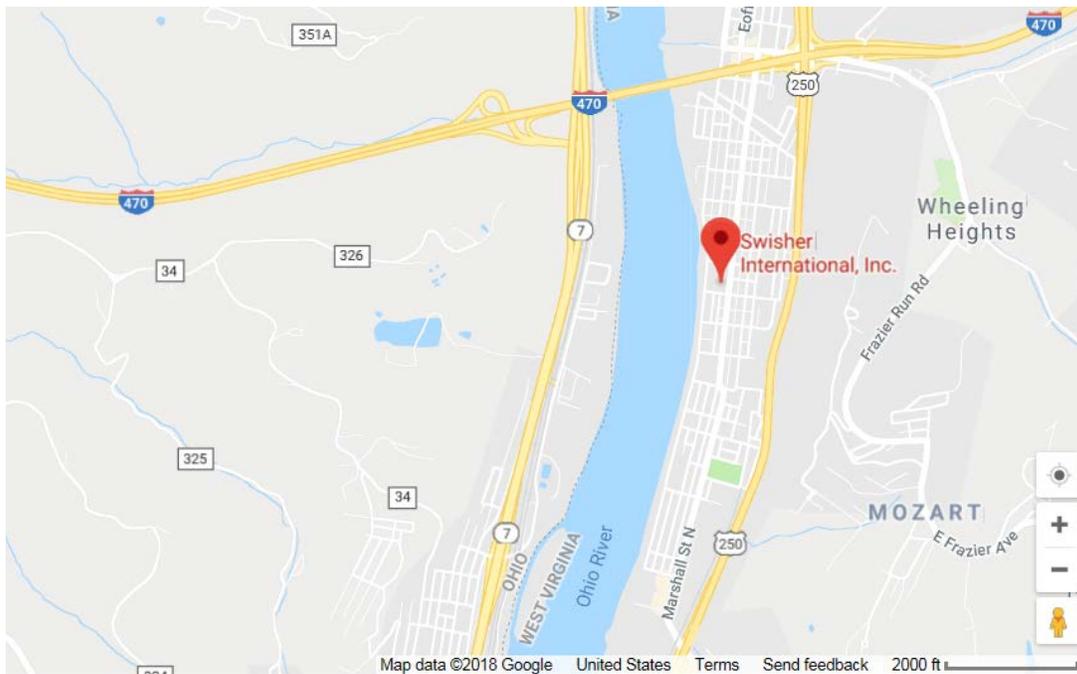
5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products

The Agency evaluated potential impacts on environmental resources that may be affected by manufacturing the new products and found no significant impacts.

5.1. Affected Environment

The affected environment includes human and natural environments surrounding the manufacturing facility. The new products are manufactured at Swisher International, Inc. facility at 4000 Water Street, Wheeling, West Virginia 26003 (Figure 1). The facility is in a mixed use industrial, commercial and residential area on the Ohio River's east bank and west of U.S. Highway 250 that is adjacent to National Forests in Ohio County. The facility is in the Ohio river valley watershed.^{2,3}

Figure 1. Location of the Manufacturing Facility



² A watershed is an area of land where all bodies of water, such as; surface water from lakes, streams, reservoirs and wetlands, the underlying ground water, and rainfall, drain to a common outlet such as the outflow of a reservoir, mouth of a bay, or any point along a stream channel. See <https://water.usgs.gov/edu/watershed.html>.

³ USGS. National Water Information System: Mapper. Available at: https://waterdata.usgs.gov/nwis/inventory?agency_code=USGS&site_no=03112500. Accessed December 27, 2018.

5.2. Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions for potential environmental impacts from manufacturing the new products based on information gathered by the Agency and the applicant's submitted information.

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that there would be no changes in the manufacturing process and therefore, manufacturing the new products would not lead to changes in air emissions to the environment from the manufacturing facility and would not require a new or revised permit.
Water resources and water quality	The applicant stated that manufacturing the new products would not lead to changes in wastewater discharges from the manufacturing facility and would not require a new or revised permit.
Land use and zoning	The applicant stated that there would be no facility expansion due to manufacturing the new products. Therefore, no changes in land use or zoning would occur as a direct impact from the proposed actions.
Biological resources	The applicant stated that there would be no facility expansion due to the new products and no changes in emissions or discharges from manufacturing the new products would be expected. Therefore, no effects to biological resources would occur as a direct impact from manufacturing the new products.
Geological features and soils	The applicant stated that there would be no facility expansion due to manufacturing the new products. Therefore, no effects on geological features or soils would occur as a direct impact from manufacturing the new products.
Solid waste and hazardous materials	The applicant stated that there would be no changes in manufacturing solid waste generation and no additional environmental controls would be needed. Therefore, the Agency does not anticipate that manufacturing the new products would lead to the presence of new chemicals in the manufacturing waste stream.
Floodplains, wetlands, and coastal zones	The applicant stated that there would be no facility expansion due to manufacturing the new products. Therefore, no effects to floodplains, wetlands, or coastal zones would occur as a direct impact manufacturing the new products.
Socioeconomics and environmental justice	<p>No changes on socioeconomics are anticipated due to manufacturing the new products. The Agency does not anticipate any impacts on employment revenue, or taxes because the new products are intended to replace similar tobacco products currently manufactured at the facility.</p> <p>No disproportionate impacts to environmental justice populations would occur as a result of manufacturing the new products because (1) a low percentage of minority (10%) and low-income populations (24.7% below poverty level) reside within 3 miles of the manufacturing facility of the new products, per 2010 U.S. Census and American Community Survey data⁴ and (2) no new chemical</p>

⁴ EPA ECHO Detailed Facility Report: Demographic profile of surrounding area (3 miles). Available at: <https://echo.epa.gov/detailed-facility-report?fid=110001930769>. Accessed December 6, 2018.

	exposure would be anticipated. In addition, the facility is not located within an Indian reservation.
Regulatory compliance	<p>The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations. The applicant stated that the facility is properly permitted by the State of West Virginia and the City of Wheeling.</p> <p>The Agency's search of U.S. Environmental Protection Agency's (EPA) Enforcement and Compliance History Online (ECHO) did not reveal any violations of the federal environmental laws and regulations.⁵ The applicant also stated that the facility complies with the Endangered Species Act and the Convention on International Trade in Endangered Species of Wild Fauna and Flora.</p>

5.3. Cumulative Impacts

The Agency does not anticipate the proposed actions to incrementally increase or change the chemicals released to the environment from the facility's tobacco manufacturing. A search in the EPA's Toxic Release Inventory (TRI) database showed that in 2017, Swisher International manufacturing facility in Wheeling, West Virginia released 750 pounds of nicotine and nicotine salts to air and transferred 2000 pounds of nicotine salts to offsite, constituting 1% of TRI releases in Ohio County.^{6,7} No other hazardous air pollutants were reported. Nicotine and nicotine salts have known adverse developmental effects.⁸ The TRI database search did not show that the manufacturing facility disposed of, treated, or released into the environment any other reportable toxicants associated with manufacturing tobacco products. In addition, EPA's ECHO database did not show that the facility released the following reportable criteria pollutants: ozone, lead, particulate matter, or sulfur dioxide, at or above the reportable threshold levels to air.

5.4. Impacts of No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing conditions of manufacturing other smokeless tobacco products, as many similar tobacco products would continue to be manufactured in the listed facility.

⁵ EPA ECHO Detailed Facility Report: U S Smokeless Tobacco Manufacturing Co LLC. Available at <https://echo.epa.gov/detailed-facility-report?fid=110001930769>. Accessed December 27, 2018.

⁶ U.S. Environmental Protection Agency (EPA). TRI Available at: https://www3.epa.gov/enviro/facts/tri/form_ra_download.html. Searched December 26, 2018.

⁷ U.S. EPA. <https://myrtk.epa.gov/info/report.jsp?IDT=TRI&ID=26003SWSHR4000W>. The site allows for searching the industrial facilities that manage toxic waste chemicals. Accessed December 26, 2018.

⁸ Chemical health effects information comes from the OSHA Carcinogen List and the TRI-CHIP datasets.

6. Potential Environmental Impacts of the Proposed Actions and Alternatives – Use of the New Products

The Agency evaluated potential impacts on environmental resources that may be affected by use of the new products and found no significant impacts.

6.1. Affected Environment

The affected environment includes human and natural environments in the United States because the marketing orders would allow for the new tobacco products to be sold to consumers nationwide.

6.2. Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions for potential environmental impacts from use of the new products based on Agency-gathered information and the applicant’s submitted information.

Environmental Resource	Analysis of Potential Impacts
Environmental justice	The new products are likely to be used by the same consumers that use existing smokeless tobacco products, competing for the same market share. Therefore, no change in impacts to environmental justice populations would be expected.

6.3. Cumulative Impacts

The Agency did not identify any actions that would lead to cumulative impacts when considered with product use under the proposed actions.

6.4. Impacts of No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing use conditions of other smokeless tobacco products in the United States, as many similar tobacco products would continue to be marketed and therefore used.

7. Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Products

The Agency evaluated potential impacts on environmental resources that may be affected by disposal of the new products and found no significant impacts.

7.1. Affected Environment

The affected environment is the entire United States because the marketing orders would allow the new tobacco products to be sold to consumers nationwide who would dispose of the used products and packaging as municipal solid waste, recycled material, or litter.

7.2. Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions for potential environmental impacts from disposal of the new products based on Agency-gathered information and the applicant's submitted information, including projected market volumes for the new and corresponding predicate products (Confidential Appendix 2).

Environmental Resource	Analysis of Potential Impacts
Biological resources	Proper disposal of the used new products and packaging in the municipal solid waste stream would not affect biological resources. Improper disposal (littering) of the used new products could lead to terrestrial wildlife having direct exposure to the used product and hazardous substances leaching to aquatic environments and soils. However, no net increase in littering would be expected because the new products would be disposed of by the same consumers who use and dispose of currently marketed smokeless tobacco products; therefore, these impacts are not considered significant.
Environmental justice	Because no significant environmental impacts were identified, there would be no disproportionate impacts to environmental justice populations from disposal of the used new products and packaging waste.
Water resources and water quality	Proper disposal of the used new products and packaging in the municipal solid waste stream would not affect water resources. Improper disposal (littering) of the used new products could result in hazardous substances leaching into water systems. However, no net increase in littering would be expected because the new products would be disposed of by the same consumers who use and dispose of currently marketed smokeless tobacco products. Therefore, these impacts are not considered significant.
Solid waste and hazardous materials	Although the new products contain additional empty plastic cans, waste generated from use of the new products would account for a small fraction of the municipal solid waste generated in the United States. ⁹ Additionally, introducing the new products is not expected to increase the nationwide use and disposal of smokeless tobacco products because the new products would compete for market share with other smokeless tobacco products.
Regulatory compliance	The new products have no features that would lead to a different rate littering for the used products compared to currently marketed smokeless tobacco products. Despite state and local ordinances, it is assumed that noncompliance (littering) would occur at the same rate for the new products as for existing smokeless tobacco products; therefore, these impacts are not considered significant.

⁹ U.S. Environmental Protection Agency. (2016). Advancing Sustainable Material Management: Facts and Figures.

7.3. Cumulative Impacts

The Agency did not identify any actions that would lead to cumulative impacts when considered with product disposal under the proposed actions.

7.4. Impacts of No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing disposal conditions of other smokeless tobacco products in the United States, as many similar tobacco products would continue to be marketed and therefore disposed of.

8. List of Preparers

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

Preparer:

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products

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

Experience: Twenty-five years in various scientific activities including seven years in NEPA practice

Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

Reviewer:

Hoshing W. Chang, Center for Tobacco Products

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

Experience: Ten years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. List of Agencies and Persons Consulted

Not applicable.

Appendix 1:

Differences Between New and Corresponding Predicate Products: Packaging Design

STN	Product Quantity (grams)		Packaging Design Change
	New Product	Predicate Product	
SE0011094 SE0011095 SE0011096	14.4 oz. (408.23 grams)	1.2 oz. (34.2 grams)	<ul style="list-style-type: none">• Addition of empty plastic can with lid identical to predicate product package that holds 1.2 oz. for refills.• Addition of polypropylene spoon for portioning.

Confidential Appendix 1:

Changes in Packaging Material Between New and Corresponding Predicate Products

STN	Component	Change
SE0011094 SE0011095 SE0011096	Tub/Can	Changed from polypropylene resin to a blend of propylene-ethylene copolymer
SE0011094 SE0011095 SE0011096	Lid	Changed from polypropylene resin to a blend of propylene-ethylene copolymer

Confidential Appendix 2:

Market Volumes for New and Corresponding Predicate Products

STN	Product	Unit	Market Volume		
			Current Year	First-Year Projection	Fifth-Year Projection
SE0011094	New Product	Plastic Tub		(b)(4)	
		Metric tons		(b)(4)	
	Predicate Product	Cans	(b)(4)		
		Metric tons	(b)(4)		
SE0011095	New Product	Plastic Tub		(b)(4)	
		Metric tons		(b)(4)	
	Predicate Product	Cans	(b)(4)		
		Metric tons	(b)(4)		
SE0011096	New Product	Plastic Tub		(b)(4)	
		Metric tons		(b)(4)	
	Predicate Product	Cans	(b)(4)		
		Metric tons	(b)(4)		
Total		Cans	(b)(4)		
		Metric tons	(b)(4)		

The applicant intends to continue marketing the predicate products after receiving marketing orders for the new products. However, introducing the new products is not expected to increase nationwide use of smokeless tobacco products, because the new products would compete for market share with other smokeless tobacco products, as well as with the predicate products.