U.S. FOOD & DRUG ADMINISTRATION

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

October 22, 2018

SUBSTANTIALLY EQUIVALENT

Swisher International Inc.
ATTENTION: Christopher Casey, Senior Vice President
and General Counsel
459 E 16th Street
Jacksonville, FL 32206-3025

FDA Submission Tracking Number (STN): MULTIPLE STNs, SEE APPENDIX A

Dear Mr. Casey:

The Food and Drug Administration (FDA) completed review of your Reports Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce (SE Report), submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the tobacco products specified in Appendix A.

Based on our review of your SE Reports, we find the new tobacco products are substantially equivalent to the corresponding eligible predicate tobacco products, specified in Appendix A.

Under the provisions of section 910 and 905(j) of the FD&C Act, you may continue to legally market the new tobacco products specified in Appendix A.

To fulfill the provisions of section 910(a)(4) of the FD&C Act, you submitted a health information summary in your SE Reports. It is your responsibility under section 910(a)(4) to make your health information summary available upon request by any person.

In accordance with 40 CFR 1506.6, we will make publicly available the finding that these marketing authorizations are in a class of actions categorically excluded under 21 CFR 25.35(a). No extraordinary circumstances exist for this action.

It is important to note our finding of substantial equivalence for your new tobacco products to an appropriate predicate tobacco product permits marketing of your new tobacco products. Our finding does not mean FDA "approved" the new products specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco products specified in Appendix A, or the labeling, as being "approved" by FDA. See Section 301(tt) of the FD&C Act.

The finding that your products are substantially equivalent to the predicate products is based upon the information you provided in your SE Reports and the standards contained in the FD&C Act, Section 910(a)(3). These marketing orders are subject to reconsideration, with notice to the manufacturer, and rescission to the extent authorized by law.

We remind you that all regulated tobacco products, including the new tobacco products specified in Appendix A, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These

requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also labeling and advertising requirements with which you must comply. It is your responsibility to ensure that the tobacco products specified in Appendix A comply with all applicable statutory and regulatory requirements, including those which may be forthcoming. FDA will monitor your compliance with these applicable statutes and regulations.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[1] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter). Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and the FDA Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; if the upload is successful, submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date (seehttp://www.fda.gov/tobaccoproducts/aboutctp/contactus/default.htm); if the due date falls on a weekend or holiday the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

If you have any questions, you may contact Jaime Golwalla, Regulatory Health Project Manager, at (301) 796 - 2878 or Jaime.Golwalla@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2018.10.22 15:33:33 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

[1] The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

Appendix A

List of new tobacco products that FDA has determined are substantially equivalent when compared to its corresponding predicate tobacco product.

Common Attributes of SE Reports	
Date of Submission:	March 21, 2011
Date of Receipt:	March 22, 2011
Product Manufacturer:	Swisher International Inc.
Product Category:	Smokeless Tobacco Products
New Tobacco Product Specific Attributes	
Submission Tracking Number:	SE0001909
Product Name:[2]	Kayak Fine Cut Wintergreen
Product Sub-Category:	Loose Moist Snuff
Package Type:	Plastic can and lid
Package Quantity:	1.2 ounces
Characterizing Flavor:	Wintergreen
Tobacco Cut Size:	(b) (4)
Predicate Tobacco Product Specific Attributes	
Product Name:[2]	Kayak Fine Cut Wintergreen
Product Sub-Category:	Loose Moist Snuff
Package Type:	Plastic can and lid
Package Quantity:	1.2 ounces
Characterizing Flavor:	Wintergreen
Eligibility Status:	Grandfathered
Tobacco Cut Size:	(b) (4)

[2] Brand/sub-brand or other commercial name used in commercial distribution.

New Tobacco Product Specific Attributes	
Submission Tracking Number:	SE0001912
Product Name:[2]	Kayak Long Cut Grape
Product Sub-Category:	Loose Moist Snuff
Package Type:	Plastic can and lid
Package Quantity:	1.2 ounces
Characterizing Flavor:	Grape
Tobacco Cut Size:	(b) (4)
Predicate Tobacco Product Specific Attributes	
Product Name:[2]	Kayak Long Cut Peach
Product Sub-Category:	Loose Moist Snuff
Package Type:	Plastic can and lid
Package Quantity:	1.2 ounces
Characterizing Flavor:	Peach
Eligibility Status:	Grandfathered
Tobacco Cut Size:	(b) (4)

New Tobacco Product Specific Attributes	
Submission Tracking Number:	SE0001919
Product Name:[2]	Kayak Pouches Wintergreen
Product Sub-Category:	Portioned Moist Snuff
Package Type:	Plastic can and lid
Package Quantity:	0.82 ounces
Characterizing Flavor:	Wintergreen
Portion Count:	15 pouches
Portion Mass:[3]	1.6 grams/pouch
Portion Length:	35 mm
Portion Width:	21 mm
Portion Thickness:	6 mm
Tobacco Cut Size:	(b) (4)
Additional Property:	Fine Cut
Predicate Tobacco Product Specific Attributes	
Product Name:[2]	Silverado Wintergreen Pouches
Product Sub-Category:	Portioned Moist Snuff
Package Type:	Plastic can and lid
Package Quantity:	0.82 ounces
Characterizing Flavor:	Wintergreen
Eligibility Status:	Grandfathered
Portion Count:	15 pouches
Portion Mass:[3]	1.6 grams/pouch
Portion Length:	35 mm
Portion Width:	21 mm
Portion Thickness:	6 mm
Tobacco Cut Size:	(b) (4)
Additional Property:	Fine Cut

[3] Providing portion mass plus two of the three portion dimensions (along with other specified properties) will allow for full identification of portioned moist snuff and snus products.