

September 30, 2019

SUBSTANTIALLY EQUIVALENT

U.S. Smokeless Tobacco Company LLC
ATTENTION: Rebecca A. Rivas, Senior Director, Regulatory Submissions
Altria Client Services LLC
2325 Bells Road
Richmond, VA 23234

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

Dear Ms. Rivas:

The Food and Drug Administration (FDA) completed review of your Reports Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce (SE Reports), 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 in compliance with the requirements of the FD&C Act and 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 introduce, or deliver for introduction into interstate commerce the 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 your environmental assessment publicly available.

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 <https://www.fda.gov/tobacco-products>. 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 (<https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal>)¹ using eSubmitter (<https://www.fda.gov/industry/fda-esubmitter>). 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 (see <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp>); 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 Iqra Javaid, MPH, Regulatory Health Project Manager, at (240) 402 - 2806 or Iqra.Javaid@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2019.09.30 13:31:13 -04'00'

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

Enclosure- Appendix A: List of New Tobacco Products Subject of This Letter

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	
Product Manufacturer:	U.S. Smokeless Tobacco Products LLC
Product Category:	Smokeless Tobacco Products
Product Sub-Category:	Loose Moist Snuff
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0004825
Date of Submission:	August 8, 2012
Date of Receipt:	August 8, 2012
Product Name: ²	Red Seal Fine Cut Wintergreen
Package Type:	Plastic Can with Metal Lid
Package Quantity:	42.53 grams
Characterizing Flavor:	Wintergreen
Tobacco cut size: ³	(b) and (b) Cut Per Inch (CPI)
Predicate Tobacco Product Specific Attributes	
Product Name: ²	Red Seal Fine Cut Wintergreen
Package Type:	Plastic Can and Plastic Lid
Package Quantity:	42.53 grams
Characterizing Flavor:	Wintergreen
Tobacco cut size: ³	(b) and (b) CPI
Eligibility Status:	Grandfathered
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0004826
Date of Submission:	August 8, 2012
Date of Receipt:	August 8, 2012
Product Name: ²	Red Seal Long Cut Mint
Package Type:	Plastic Can with Metal Lid
Package Quantity:	42.53 grams
Characterizing Flavor:	Mint
Tobacco cut size:	(b) CPI
Predicate Tobacco Product Specific Attributes	
Product Name: ²	Red Seal Long Cut Mint
Package Type:	Plastic Can and Plastic Lid
Package Quantity:	42.524 grams
Characterizing Flavor:	Mint
Tobacco cut size: ⁴	(b) and (b) CPI
Eligibility Status:	Grandfathered

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

³ Applicant claims that the new product and predicate product have identical tobacco base comprised of 67.2% tobacco cut at (b) CPI and 32.8% tobacco cut at (b) CPI.

⁴ Applicant claims that the predicate product has a tobacco base comprised of 70.1% tobacco cut at (b) CPI and 29.9% tobacco cut at (b) CPI.

New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0004827
Date of Submission:	August 8, 2012
Date of Receipt:	August 8, 2012
Product Name: ²	Red Seal Long Cut Natural
Package Type:	Plastic Can with Metal Lid
Package Quantity:	42.53 grams
Characterizing Flavor:	None
Tobacco cut size:	(b) CPI
Predicate Tobacco Product Specific Attributes	
Product Name: ²	Red Seal Long Cut Natural
Package Type:	Plastic Can and Plastic Lid
Package Quantity:	42.524 grams
Characterizing Flavor:	None
Tobacco cut size:	(b) CPI
Eligibility Status:	Grandfathered
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0004828
Date of Submission:	August 8, 2012
Date of Receipt:	August 8, 2012
Product Name: ²	Red Seal Long Cut Straight
Package Type:	Plastic Can with Metal Lid
Package Quantity:	42.53 grams
Characterizing Flavor:	None
Tobacco cut size:	(b) CPI
Predicate Tobacco Product Specific Attributes	
Product Name: ²	Red Seal Long Cut Straight
Package Type:	Plastic Can and Plastic Lid
Package Quantity:	42.524 grams
Characterizing Flavor:	None
Tobacco cut size: ⁴	(b) and (b) CPI
Eligibility Status:	Grandfathered
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0004829
Date of Submission:	August 8, 2012
Date of Receipt:	August 8, 2012
Product Name: ²	Red Seal Long Cut Wintergreen
Package Type:	Plastic Can with Metal Lid
Package Quantity:	42.53 grams
Characterizing Flavor:	Wintergreen
Tobacco cut size:	(b) CPI
Predicate Tobacco Product Specific Attributes	
Product Name: ²	Red Seal Long Cut Wintergreen
Package Type:	Plastic Can and Plastic Lid
Package Quantity:	42.524 grams
Characterizing Flavor:	Wintergreen
Tobacco cut size:	(b) CPI
Eligibility Status:	Grandfathered

New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0004875
Date of Submission:	August 30, 2012
Date of Receipt:	August 30, 2012
Product Name: ²	Husky Fine Cut Natural
Package Type:	Plastic Can with Metal Lid
Package Quantity:	34.02 grams
Characterizing Flavor:	None
Tobacco cut size: ³	(b) and (b) CPI
Predicate Tobacco Product Specific Attributes	
Product Name: ²	Husky Fine Cut Natural
Package Type:	Plastic Can and Plastic Lid
Package Quantity:	34.02 grams
Characterizing Flavor:	None
Tobacco cut size: ³	(b) and (b) CPI
Eligibility Status:	Grandfathered
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0004876
Date of Submission:	August 30, 2012
Date of Receipt:	August 30, 2012
Product Name: ²	Husky Fine Cut Wintergreen
Package Type:	Plastic Can with Metal Lid
Package Quantity:	34.02 grams
Characterizing Flavor:	Wintergreen
Tobacco cut size: ³	(b) and (b) CPI
Predicate Tobacco Product Specific Attributes	
Product Name: ²	Husky Fine Cut Wintergreen
Package Type:	Plastic Can and Plastic Lid
Package Quantity:	34.02 grams
Characterizing Flavor:	Wintergreen
Tobacco cut size: ³	(b) and (b) CPI
Eligibility Status:	Grandfathered
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0004877
Date of Submission:	August 30, 2012
Date of Receipt:	August 30, 2012
Product Name: ²	Husky Long Cut Mint
Package Type:	Plastic Can with Metal Lid
Package Quantity:	34.02 grams
Characterizing Flavor:	Mint
Tobacco cut size:	(b) CPI
Predicate Tobacco Product Specific Attributes	
Product Name: ²	Husky Long Cut Mint
Package Type:	Plastic Can and Plastic Lid
Package Quantity:	34.02 grams
Characterizing Flavor:	Mint
Tobacco cut size: ⁴	(b) and (b) CPI
Eligibility Status:	Grandfathered

New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0004878
Date of Submission:	August 30, 2012
Date of Receipt:	August 30, 2012
Product Name: ²	Husky Long Cut Natural
Package Type:	Plastic Can with Metal Lid
Package Quantity:	34.02 grams
Characterizing Flavor:	None
Tobacco cut size:	(b) CPI
Predicate Tobacco Product Specific Attributes	
Product Name: ²	Husky Long Cut Natural
Package Type:	Plastic Can and Plastic Lid
Package Quantity:	34.02 grams
Characterizing Flavor:	None
Tobacco cut size:	(b) CPI
Eligibility Status:	Grandfathered
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0004879
Date of Submission:	August 30, 2012
Date of Receipt:	August 30, 2012
Product Name: ²	Husky Long Cut Straight
Package Type:	Plastic Can with Metal Lid
Package Quantity:	34.02 grams
Characterizing Flavor:	None
Tobacco cut size:	(b) CPI
Predicate Tobacco Product Specific Attributes	
Product Name: ²	Husky Long Cut Straight
Package Type:	Plastic Can and Plastic Lid
Package Quantity:	34.02 grams
Characterizing Flavor:	None
Tobacco cut size: ⁴	(b) and (b) CPI
Eligibility Status:	Grandfathered
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0004880
Date of Submission:	August 30, 2012
Date of Receipt:	August 30, 2012
Product Name: ²	Husky Long Cut Wintergreen
Package Type:	Plastic Can with Metal Lid
Package Quantity:	34.02 grams
Characterizing Flavor:	Wintergreen
Tobacco cut size:	(b) CPI
Predicate Tobacco Product Specific Attributes	
Product Name: ²	Husky Long Cut Wintergreen
Package Type:	Plastic Can and Plastic Lid
Package Quantity:	34.02 grams
Characterizing Flavor:	Wintergreen
Tobacco cut size:	(b) CPI
Eligibility Status:	Grandfathered