

November 05, 2018

SUBSTANTIALLY EQUIVALENT

Swedish Match USA, Inc.
ATTENTION: Gerard J. Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 E Cary Street, Suite 1600
Richmond, VA 23219

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

Dear Mr. Roerty:

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 in compliance with the requirements of the FD&C Act and substantially equivalent to the corresponding eligible predicate tobacco products,¹ 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^{Error! Bookmark not defined.}. 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

¹ For SE0011034 - SE0011038, SE0011040, and SE0011042, in addition to comparing the new tobacco product to the predicate tobacco products named by the applicant, FDA also compared the new tobacco product in these SE Reports to the corresponding grandfathered tobacco product specified in Appendix A. Although the new product has different characteristics than the corresponding grandfathered tobacco product, FDA found that those differences do not cause the new tobacco product to raise different questions of public health, and thus the new tobacco product is also substantially equivalent to the corresponding grandfathered product.

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>)² 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 (see <http://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.

² The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

If you have any questions, you may contact Shireen Fotelargias, Regulatory Health Project Manager, at (240) 402 - 0435 or Shireen.Fotelargias@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S

Date: 2018.11.05 10:03:36 -05'00'

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

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 24, 2015
Date of Receipt:	March 24, 2015
Product Manufacturer:	Swedish Match USA Inc.
Product Category:	Smokeless Tobacco Products
Product Sub-Category:	Loose Moist Snuff
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0011034
Product Name: ³	Longhorn Fine Cut Natural, 204.12 g
Package Type:	Plastic can and lid
Package Quantity:	204.12 grams
Characterizing Flavor:	Natural
Tobacco cut size:	(b) (4) CPI ⁴
Predicate Tobacco Product Specific Attributes	
Product Name: ³	Longhorn Fine Cut Natural 34.02 g
Package Type:	Plastic can and lid
Package Quantity:	34.02 grams
Characterizing Flavor:	Natural
Eligibility Status:	Previously found SE under SE0000098
Tobacco cut size:	(b) (4) CPI ⁴



Common Attributes of SE Reports	
Date of Submission:	March 24, 2015
Date of Receipt:	March 24, 2015
Product Manufacturer:	Swedish Match USA Inc.
Product Category:	Smokeless Tobacco Products
Product Sub-Category:	Loose Moist Snuff
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0011035
Product Name: ³	Longhorn Fine Cut Wintergreen, 408.24 g
Package Type:	Plastic can and lid
Package Quantity:	408.24 grams
Characterizing Flavor:	Wintergreen
Tobacco cut size:	(b) (4) CPI ⁴
Predicate Tobacco Product Specific Attributes	
Product Name: ³	Longhorn Fine Cut Wintergreen 34.02 g
Package Type:	Plastic can and lid
Package Quantity:	34.02 grams
Characterizing Flavor:	Wintergreen
Eligibility Status:	Previously found SE under SE0000101
Tobacco cut size:	(b) (4) CPI ⁴



³ Brand/sub-brand or other commercial name used in commercial distribution.

⁴ Cuts per inch (CPI)



Common Attributes of SE Reports	
Date of Submission:	March 24, 2015
Date of Receipt:	March 24, 2015
Product Manufacturer:	Swedish Match USA Inc.
Product Category:	Smokeless Tobacco Products
Product Sub-Category:	Loose Moist Snuff
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0011036
Product Name: ³	Longhorn Fine Cut Wintergreen, 204.12 g
Package Type:	Plastic can and lid
Package Quantity:	204.12 grams
Characterizing Flavor:	Wintergreen
Tobacco cut size:	(b) (4) CPI ⁴
Predicate Tobacco Product Specific Attributes	
Product Name: ³	Longhorn Fine Cut Wintergreen 34.02 g
Package Type:	Plastic can and lid
Package Quantity:	34.02 grams
Characterizing Flavor:	Wintergreen
Eligibility Status:	Previously found SE under SE0000101
Tobacco cut size:	(b) (4) CPI ⁴



Common Attributes of SE Reports	
Date of Submission:	March 24, 2015
Date of Receipt:	March 24, 2015
Product Manufacturer:	Swedish Match USA Inc.
Product Category:	Smokeless Tobacco Products
Product Sub-Category:	Loose Moist Snuff
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0011037
Product Name: ³	Longhorn Long Cut Natural, 408.24 g
Package Type:	Plastic can and lid
Package Quantity:	408.24 grams
Characterizing Flavor:	Natural
Tobacco cut size:	(b) (4) CPI ⁴
Predicate Tobacco Product Specific Attributes	
Product Name: ³	Longhorn Long Cut Natural 34.02 g
Package Type:	Plastic can and lid
Package Quantity:	34.02 grams
Characterizing Flavor:	Natural
Eligibility Status:	Previously found SE under SE0000099
Tobacco cut size:	(b) (4) CPI ⁴

Common Attributes of SE Reports	
Date of Submission:	March 24, 2015
Date of Receipt:	March 24, 2015
Product Manufacturer:	Swedish Match USA Inc.
Product Category:	Smokeless Tobacco Products
Product Sub-Category:	Loose Moist Snuff
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0011038
Product Name: ³	Longhorn Long Cut Natural, 204.12 g
Package Type:	Plastic can and lid
Package Quantity:	204.12 grams
Characterizing Flavor:	Natural
Tobacco cut size:	 CPI ⁴
Predicate Tobacco Product Specific Attributes	
Product Name: ³	Longhorn Long Cut Natural 34.02 g
Package Type:	Plastic can and lid
Package Quantity:	34.02 grams
Characterizing Flavor:	Natural
Eligibility Status:	Previously found SE under SE0000099
Tobacco cut size:	 CPI ⁴

Common Attributes of SE Reports	
Date of Submission:	March 24, 2015
Date of Receipt:	March 24, 2015
Product Manufacturer:	Swedish Match USA Inc.
Product Category:	Smokeless Tobacco Products
Product Sub-Category:	Loose Moist Snuff
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0011040
Product Name: ³	Longhorn Long Cut Straight, 204.12 g
Package Type:	Plastic can and lid
Package Quantity:	204.12 grams
Characterizing Flavor:	Straight
Tobacco cut size:	 CPI ⁴
Predicate Tobacco Product Specific Attributes	
Product Name: ³	Longhorn Long Cut Straight
Package Type:	Plastic can and lid
Package Quantity:	34.02 grams
Characterizing Flavor:	Straight
Eligibility Status:	Previously found SE under SE0003404
Tobacco cut size:	 CPI ⁴

Common Attributes of SE Reports	
Date of Submission:	March 24, 2015
Date of Receipt:	March 24, 2015
Product Manufacturer:	Swedish Match USA Inc.
Product Category:	Smokeless Tobacco Products
Product Sub-Category:	Loose Moist Snuff
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0011042
Product Name: ³	Longhorn Long Cut Wintergreen, 204.12 g
Package Type:	Plastic can and lid
Package Quantity:	204.12 grams
Characterizing Flavor:	Wintergreen
Tobacco cut size:	 CPI ⁴
Predicate Tobacco Product Specific Attributes	
Product Name: ³	Longhorn Long Cut Wintergreen 34.02 g
Package Type:	Plastic can and lid
Package Quantity:	34.02 grams
Characterizing Flavor:	Wintergreen
Eligibility Status:	Previously found SE under SE0000100
Tobacco cut size:	 CPI ⁴

Common Attributes of SE Reports	
Date of Submission:	March 24, 2015
Date of Receipt:	March 24, 2015
Product Manufacturer:	Swedish Match USA Inc.
Product Category:	Smokeless Tobacco Products
Product Sub-Category:	Loose Moist Snuff
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0011043
Product Name: ³	Longhorn Long Cut Mint, 408.24 g
Package Type:	Plastic can and lid
Package Quantity:	408.24 grams
Characterizing Flavor:	Mint
Tobacco cut size:	 CPI ⁴
Predicate Tobacco Product Specific Attributes	
Product Name: ³	Longhorn Long Cut Mint
Package Type:	Plastic can and lid
Package Quantity:	37.42 grams
Characterizing Flavor:	Mint
Eligibility Status:	Grandfathered
Tobacco cut size:	 CPI ⁴

Common Attributes of SE Reports	
Date of Submission:	March 24, 2015
Date of Receipt:	March 24, 2015
Product Manufacturer:	Swedish Match USA Inc.
Product Category:	Smokeless Tobacco Products
Product Sub-Category:	Loose Moist Snuff
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0011044
Product Name:³	Longhorn Long Cut Mint, 204.12 g
Package Type:	Plastic can and lid
Package Quantity:	204.12 grams
Characterizing Flavor:	Mint
Tobacco cut size:	 CPI ⁴
Predicate Tobacco Product Specific Attributes	
Product Name:³	Longhorn Long Cut Mint
Package Type:	Plastic can and lid
Package Quantity:	37.42 grams
Characterizing Flavor:	Mint
Eligibility Status:	Grandfathered
Tobacco cut size:	 CPI ⁴