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

November 16, 2018

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 Number (STN): SE0014737-SE0014738 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 opted not to provide an adequate summary of any health information related to the new tobacco products with your applications but stated that such information will be available upon request by any person. Consistent with the requirements of Section 910(a)(4), you may wish to consider providing the following when information is requested:

A. A copy of your final SE Reports upon which our order was based, redacted only to the extent necessary to exclude patient identifiers, and trade secret and confidential commercial information as defined in 21 CFR § 20.61 and 20.63 and;
B. Any research or data you have in your possession or otherwise know of specifically regarding the adverse health effects of the new tobacco product or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name]”.

Alternatively, you may provide the following when information is requested:

A. Description of the new tobacco products;
B. Description of the predicate tobacco products;
C. List of all differences in characteristics between the predicate and new tobacco products;

D. Summary of the evidence and scientific rationale concerning why the differences in characteristics do not raise different questions of public health; and
E. Any research or data you have in your possession or otherwise know of regarding the adverse health effects of the new tobacco product or the following statement if such statement is accurate: "[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name]".

There may be other accurate, complete and not false or misleading ways to satisfy the requirements of Section 910(a)(4) not included above. If you wish to discuss other ways to meet the requirements of 910(a)(4), submit a meeting request to FDA.

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 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).

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

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/abouctp/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 Arielle Patno, Regulatory Health Project Manager, at (301) 796 - 6861 or Arielle.Patno@fda.hhs.gov.

Sincerely,

Digitally signed by Glen D. Jones -S
Date: 2018.11.16 17:33:12 -05'00'

For 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:	May 31, 2018
Date of Receipt:	May 31, 2018
Product Manufacturer:	U.S. Smokeless Tobacco Company LLC
Product Category:	Smokeless Tobacco Products
Product Sub-Category:	Loose Moist Snuff
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0014737
Product Name:[2]	Copenhagen Long Cut Straight
Package Type:	Fiberboard can and metal lid
Package Quantity:	34.02 grams
Characterizing Flavor:	None
Tobacco Cut Size:	(b) (4) Cuts Per Inch (CPI)
Predicate Tobacco Product Specific Attributes	
Product Name: [2]	Copenhagen Long Cut Straight
Package Type:	Fiberboard can and metal lid
Package Quantity:	34.02 grams
Characterizing Flavor:	None
Tobacco Cut Size:	(b) (4) CPI
Eligibility Status:	Grandfathered
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0014738
Product Name:[2]	Copenhagen Snuff Fine Cut
Package Type:	Fiberboard can and metal lid
Package Quantity:	34.02 grams
Characterizing Flavor:	None
Tobacco Cut Size:	(b) (4) CPI
Predicate Tobacco Product Specific Attributes	
Product Name:[2]	Copenhagen Snuff Fine Cut
Package Type:	Fiberboard can and metal lid
Package Quantity:	34.02 grams
Characterizing Flavor:	None
Tobacco Cut Size:	(b) (4) CPI
Eligibility Status:	Grandfathered

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