



March 29, 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 Number (STN): SE0004824

Dear Ms. Rivas:

The Food and Drug Administration (FDA) completed review of your Report 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 following tobacco product:

New Tobacco Product

Date of Submission:	August 8, 2012
Date of Receipt:	August 8, 2012
Product Manufacturer:	U.S. Smokeless Tobacco Company LLC
Product Name:¹	Red Seal Fine Cut Natural
Product Category:	Smokeless Tobacco Products
Product Sub-Category:	Loose Moist Snuff
Package Type:	Plastic Can and Metal Lid
Package Quantity:	42.53 grams
Characterizing Flavor:	None
Tobacco Cut Size:	Not Provided ²

Based on our review of your SE Report, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and substantially equivalent to the following eligible predicate tobacco product:

¹ Brand/sub-brand or other commercial name used in commercial distribution.

² The applicant did not provide a target value for the tobacco cut size for the new tobacco product; however, they provided information on the manufacturing steps, including the tobacco blend composition, machine cutter setting, the number of cuts, the sieve mesh, and the milling; tobacco blend composition of (b) (4)

The applicant stated that these tobacco cutting parameters are identical between the new and predicate tobacco products. In this case, FDA determined that no additional information regarding tobacco cut size was necessary to compare the new and predicate tobacco products.

Predicate Tobacco Product

Product Manufacturer:	U.S. Smokeless Tobacco Company LLC
Product Name:¹	Red Seal Fine Cut Natural (2007)
Product Category:	Smokeless Tobacco Products
Product Sub-Category:	Loose Moist Snuff
Package Type:	Plastic Can and Lid
Package Quantity:	42.53 grams
Characterizing Flavor:	None
Eligibility Type:	Grandfathered
Tobacco Cut Size:	Not Provided ³

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 product specified above.

To fulfill the provisions of section 910(a)(4) of the FD&C Act, you submitted a health information summary in your SE Report. 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 product specified above to an appropriate predicate tobacco product permits marketing of your new tobacco product. Our finding does not mean FDA “approved” the new product specified above; therefore, you may not promote or in any way represent the new tobacco product specified above, or its labeling, as being “approved” by FDA. See Section 301(tt) of the FD&C Act.

The finding that your product is substantially equivalent to the predicate product is based upon the information you provided in your SE Report and the standards contained in the FD&C Act, Section 910(a)(3). This marketing order is 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 product specified above, 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 product specified above complies 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.

³ The applicant did not provide a target value for the tobacco cut size for the predicate tobacco product; however, they stated that the following tobacco cutting parameters are identical between the new and predicate tobacco products: tobacco blend composition, machine cutter setting, the number of cuts, the sieve mesh, and the milling. In this case, FDA determined that no additional information regarding tobacco cut size was necessary to compare the new and predicate tobacco products.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal (<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm>)⁴ 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.

If you have any questions, you may contact Ebony Jackson, M.P.H., Regulatory Health Project Manager, at (240) 402 - 4499 or Ebony.Jackson@fda.hhs.gov.

Sincerely,

**Digitally signed by Matthew R. Holman -S
Date: 2019.03.29 11:42:26 -04'00'**

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

⁴ The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.