



August 02, 2021

SUBSTANTIALLY EQUIVALENT

US Flue-Cured Tobacco Growers, Inc.
Attention: Brian Mosely, Quality Manager
250 Crown Boulevard
Timberlake, NC 27583

FDA Submission Tracking Numbers (STNs): SE0018586, SE0019884-SE0019897, see Appendix A

Dear Mr. Mosely:

We completed our review of your SE Reports¹ and determined that the new tobacco products are substantially equivalent to the corresponding predicate tobacco products listed in Appendix A and are in compliance with the requirements of the FD&C Act. 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 new tobacco products subject of this letter.

Our finding does not mean we “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).

For information on how to fulfill the provisions of section 910(a)(4) of the FD&C Act, refer to Appendix B.

In accordance with 40 CFR 1506.6, we will make your Environmental Assessment (EA) publicly available.

All regulated tobacco products, including the tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure the tobacco products specified in Appendix A complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

¹ Substantially Equivalent (SE) Reports submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

If you have any questions, please contact Crystal Caesar, B.S., Regulatory Health Project Manager, at (240) 402-4793 or Crystal.Caesar@fda.hhs.gov.

Sincerely,

Todd Cecil, Ph.D.
Deputy Director
Office of Science
Center for Tobacco Products

Enclosures:

Appendix A – New and Corresponding Predicate Tobacco Products Subject of This Letter
Appendix B – Health Information Summary

Appendix A
New and Corresponding Predicate Tobacco Products Subject of This Letter

Common Attributes of SE Reports		
Submission date	September 8, 2020	
Receipt date	September 8, 2020	
Product manufacturer	US Flue-Cured Tobacco Growers, Inc.	
Product category	Pipe Tobacco Products	
Product subcategory	Pipe Tobacco Filler	
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0018586	Not Applicable
Product name ²	1839 Pipe Tobacco Blue 6 oz. Bag	1839 RYO Mild Flavor 6oz. Bag
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not Applicable	Grandfathered
Package type	Bag	Bag
Package quantity	6 oz.	6 oz.
Characterizing flavor	None	None
STN	SE0019884	Not Applicable
Product name ²	1839 Pipe Tobacco Blue 16oz. Bag	1839 RYO Mild Flavor 16oz. Bag
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not Applicable	Grandfathered
Package type	Bag	Bag
Package quantity	16 oz.	16 oz.
Characterizing flavor	None	None
STN	SE0019885	Not Applicable
Product name ²	1839 Pipe Tobacco Green 6oz. Bag	1839 RYO Menthol 6oz. Bag
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	6 oz.	6 oz.
Characterizing flavor	Menthol	Menthol

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

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0019886	Not Applicable
Product name ²	1839 Pipe Tobacco Green 16oz. Bag	1839 RYO Menthol 16oz. Bag
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	16 oz.	16 oz.
Characterizing flavor	Menthol	Menthol
STN	SE0019887	Not Applicable
Product name ²	1839 Pipe Tobacco Red 6oz. Bag	1839 RYO Full Flavor 6oz. Bag
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	6 oz.	6 oz.
Characterizing flavor	None	None
STN	SE0019888	Not Applicable
Product name ²	1839 Pipe Tobacco Red 16oz. Bag	1839 RYO Full Flavor 16oz. Bag
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	16 oz.	16 oz.
Characterizing flavor	None	None
STN	SE0019889	Not Applicable
Product name ²	Traffic Pipe Tobacco Blue 16oz. Bag	1839 RYO Mild Flavor 16oz. Bag
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	16 oz.	16 oz.
Characterizing flavor	None	None
STN	SE0019890	Not Applicable
Product name ²	Traffic Pipe Tobacco Green 16oz. Bag	1839 RYO Menthol 16oz. Bag
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	16 oz.	16 oz.
Characterizing flavor	Menthol	Menthol

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0019891	Not Applicable
Product name ²	Traffic Pipe Tobacco Red 16oz. Bag	1839 RYO Full Flavor 16oz. Bag
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	16 oz.	16 oz.
Characterizing flavor	None	None
STN	SE0019892	Not Applicable
Product name ²	Wildhorse Pipe Tobacco Blue 6oz. Bag	1839 RYO Mild Flavor 6oz. Bag
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	6 oz.	6 oz.
Characterizing flavor	None	None
STN	SE0019893	Not Applicable
Product name ²	Wildhorse Pipe Tobacco Blue 16oz. Bag	1839 RYO Mild Flavor 16oz. Bag
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	16 oz.	16 oz.
Characterizing flavor	None	None
STN	SE0019894	Not Applicable
Product name ²	Wildhorse Pipe Tobacco Green 6oz. Bag	1839 RYO Menthol 6oz. Bag
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	6 oz.	6 oz.
Characterizing flavor	Menthol	Menthol
STN	SE0019895	Not Applicable
Product name ²	Wildhorse Pipe Tobacco Green 16oz. Bag	1839 RYO Menthol 16oz. Bag
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	16 oz.	16 oz.
Characterizing flavor	Menthol	Menthol

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0019896	Not Applicable
Product name ²	Wildhorse Pipe Tobacco Red 6oz. Bag	1839 RYO Full Flavor 6oz. Bag
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	6 oz.	6 oz.
Characterizing flavor	None	None
STN	SE0019897	Not Applicable
Product name ²	Wildhorse Pipe Tobacco Red 16oz. Bag	1839 RYO Full Flavor 16oz. Bag
Product category	Pipe Tobacco Products	Roll-Your-Own Tobacco Products
Product subcategory	Pipe Tobacco Filler	Roll-Your-Own Tobacco Filler
Eligibility status	Not applicable	Grandfathered
Package type	Bag	Bag
Package quantity	16 oz.	16 oz.
Characterizing flavor	None	None

Appendix B
Health Information Summary

Your SE Reports did not provide a summary of any health information related to the new tobacco products, required by section 910(a)(4) of the FD&C Act; however, your SE Reports stated that such information will be available upon request to 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 the Substantially Equivalent 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.
- B. Any research or data you have in your possession or otherwise know of specifically regarding the adverse health effects of the new tobacco products, 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:

- Description of the new tobacco products
- Description of the predicate tobacco products
- List of all differences in characteristics between the new and predicate tobacco products
- Summary of the evidence and scientific rationale concerning why the differences in characteristics do not raise different questions of public health
- 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 section 910(a)(4), submit a meeting request to us