



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

June 30, 2021

SUBSTANTIALLY EQUIVALENT

Sutliff Tobacco Company LLC
Attention: Jeremy W. McKenna, President
600 Perdue Avenue
Richmond, VA 23224

FDA Submission Tracking Numbers (STNs): Multiple STNs, see Appendix A

Dear Mr. McKenna:

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 Tishelle Ogunfeditimi, MPH, Regulatory Health Project Manager, at (301) 837-7397 or Tishelle.Ogunfeditimi@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S

Date: 2021.06.30 15:00:56 -04'00'

Matthew R. Holman, Ph.D.

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	April 22, 2020	
Receipt date	April 22, 2020	
Product manufacturer	Sutliff Tobacco Company LLC	
Product category	Pipe Tobacco Products	
Product subcategory	Pipe Tobacco Filler	
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016218	GF1907817
Product name	600 USA 1.5 oz ²	600 USA ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 ounces (oz)	1 (lb) ³
Characterizing flavor	Vanilla	Vanilla
STN	SE0016235	GF1907669
Product name	10 Natural Cavendish 8 oz ²	10 Natural Cavendish ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb ³
Characterizing flavor	None	None
STN	SE0016236	GF1907670
Product name	11 Whiskey Cavendish 1.5 oz ²	11 Whiskey Cavendish ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb ³
Characterizing flavor	Whiskey	Whiskey
STN	SE0016237	GF1907670
Product name	11 Whiskey Cavendish 8 oz ²	11 Whiskey Cavendish ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb ³
Characterizing flavor	Whiskey	Whiskey

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

³ One pound is equal to 16 ounces

STN	SE0016238	GF1907671
Product name	12 Cherry Cavendish 8 oz ²	12 Cherry Cavendish ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb ³
Characterizing flavor	Cherry	Cherry
STN	SE0016239	GF1907672
Product name	13 Tropic Cavendish 1.5 oz ²	13 Tropic Cavendish ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb ³
Characterizing flavor	Mango	Mango
STN	SE0016240	GF1907672
Product name	13 Tropic Cavendish 8 oz ²	13 Tropic Cavendish ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb ³
Characterizing flavor	Mango	Mango
STN	SE0016241	GF1907673
Product name	14 Maple Cavendish 8 oz ²	14 Maple Cavendish ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb ³
Characterizing flavor	Maple	Maple
STN	SE0016242	GF1907675
Product name	16 English Toffee 1.5 oz ²	16 English Toffee ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb ³
Characterizing flavor	Toffee	Toffee
STN	SE0016243	GF1908274
Product name	18 Mellow 1.5 oz ²	QFC Mellow N Mild 16 oz ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb ³
Characterizing flavor	Hazelnut	Hazelnut

STN	SE0016244	GF1908274
Product name	18 Mellow 8 oz ²	QFC Mellow N Mild 16 oz ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb ³
Characterizing flavor	Hazelnut	Hazelnut
STN	SE0016245	GF1907846
Product name	64K Embassy 1.5 oz ²	64K Embassy ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb ³
Characterizing flavor	Vanilla	Vanilla
STN	SE0016246	GF1907849
Product name	101 Black Kathy 1.5 oz ²	101 Black Kathy ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb ³
Characterizing flavor	Spice	Spice
STN	SE0016247	GF1907851
Product name	103 Whiskey Galore 1.5 oz ²	103 Whiskey Galore ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb ³
Characterizing flavor	Whiskey	Whiskey
STN	SE0016248	GF1907851
Product name	103 Whiskey Galore 8 oz ²	103 Whiskey Galore ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb ³
Characterizing flavor	Whiskey	Whiskey
STN	SE0016249	GF1907852
Product name	105 Royal Viking 1.5 oz ²	105 Royal Viking ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb ³
Characterizing flavor	Vanilla	Vanilla

STN	SE0016250	GF1907853
Product name	111 Blue Grass 1.5 oz ²	111 Blue Grass ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb ³
Characterizing flavor	Vanilla	Vanilla
STN	SE0016251	GF1907853
Product name	111 Blue Grass 8 oz ²	111 Blue Grass ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb ³
Characterizing flavor	Vanilla	Vanilla
STN	SE0016252	GF1907855
Product name	131 Vanilla Maple 1.5 oz ²	131 Vanilla Maple ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb ³
Characterizing flavor	Vanilla maple	Vanilla maple
STN	SE0016253	GF1907855
Product name	131 Vanilla Maple 8 oz ²	131 Vanilla Maple ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb ³
Characterizing flavor	Vanilla maple	Vanilla maple
STN	SE0016254	GF1907981
Product name	200 Red Wine 1.5 oz ²	200 Red Wine ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb ³
Characterizing flavor	Red Wine	Red Wine
STN	SE0016255	GF1907982
Product name	201 Sangria 1.5 oz ²	201 Sangria ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb ³
Characterizing flavor	Sangria	Sangria

STN	SE0016256	GF1907982
Product name	201 Sangria 8 oz ²	201 Sangria ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb ³
Characterizing flavor	Sangria	Sangria
STN	SE0016257	GF1907983
Product name	203 Coffee 1.5 oz ²	203 Coffee ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb ³
Characterizing flavor	Coffee	Coffee
STN	SE0016258	GF1907983
Product name	203 Coffee 8 oz ²	203 Coffee ²
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb ³
Characterizing flavor	Coffee	Coffee

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.