



December 20, 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 905j 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 301tt of the FD&C Act.

For information on how to fulfill the provisions of section 910a4 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 905j 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: 2021.12.20 11:51:58 -05'00'

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^{2,3}

New and Corresponding Predicate Tobacco Products Subject of This Letter

Common Attributes of SE Reports		
Submission date	April 24, 2020	
Receipt date	April 24, 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	SE0016453	GF1908023
Product name	SPS-3 Cherry 1.5 oz	SPS-3 Cherry
Eligibility status	Not applicable	Grandfathered
Package type	Plastic pouch	Plastic bag
Package quantity	1.5 ounces (oz)	1 pound (lb) ³
Characterizing flavor	Cherry	Cherry
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016454	GF1908023
Product name	SPS-3 Cherry 8 oz	SPS-3 Cherry
Eligibility status	Not applicable	Grandfathered
Package type	Plastic bag	Plastic bag
Package quantity	8 oz	1 lb
Characterizing flavor	Cherry	Cherry
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016455	GF1908024
Product name	SPS-4 Mango 1.5 oz	SPS-4 Mango
Eligibility status	Not applicable	Grandfathered
Package type	Plastic pouch	Plastic bag
Package quantity	1.5 oz	1 lb
Characterizing flavor	Mango	Mango
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016456	GF1908024
Product name	SPS-4 Mango 8 oz	SPS-4 Mango
Eligibility status	Not applicable	Grandfathered
Package type	Plastic bag	Plastic bag
Package quantity	8 oz	1 lb
Characterizing flavor	Mango	Mango
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016457	GF1908025
Product name	SPS-9 Vanilla Creme 1.5 oz	SPS-9 Vanilla Crème
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic pouch	Plastic bag
Package quantity	1.5 oz	1 lb
Characterizing flavor	Vanilla	Vanilla

² Brand/sub-brand or other commercial name used in commercial distribution.³ One pound is equal to 16 ounces.

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016459	GF1908026
Product name	SPS-9F French Vanilla 1.5 oz	SPS-9F French Vanilla
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic pouch	Plastic bag
Package quantity	1.5 oz	1 lb
Characterizing flavor	Vanilla	Vanilla
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016468	GF1908036
Product name	SPS-22 Bright Burley & Virginia 8 oz	SPS-22 Bright Burley & Virginia
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic bag	Plastic bag
Package quantity	8 oz	1 lb
Characterizing flavor	None	None
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016474	GF1908050
Product name	SPS-39 Emerald Isle 1.5 oz	SPS-39 Emerald Isle
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic pouch	Plastic bag
Package quantity	1.5 oz	1 lb
Characterizing flavor	None	None
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016480	GF1908055
Product name	SPS-702 Pressed Burley 1.5 oz	SPS-702 Pressed Burley
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic pouch	Plastic bag
Package quantity	1.5 oz	1 lb
Characterizing flavor	None	None
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016482	GF1908056
Product name	SPS-2000 Sunset Rum 8 oz	SPS-2000 Sunset Rum
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic bag	Plastic bag
Package quantity	8 oz	1 lb
Characterizing flavor	Rum	Rum
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016484	GF1908058
Product name	SPS-2003 Strawberry Delight 8 oz	SPS-2003 Strawberry Delight
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic bag	Plastic bag
Package quantity	8 oz	1 lb
Characterizing flavor	Strawberry	Strawberry

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016485	GF1908059
Product name	SPS-2004 Kahlua Amaretto 1.5 oz	SPS-2004 Kahlua Amaretto
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic pouch	Plastic bag
Package quantity	1.5 oz	1 lb
Characterizing flavor	Amaretto	Amaretto
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016491	GF1907709
Product name	TS1 Bright Virginia Ribbon 1.5 oz	TS1 Bright Virginia Ribbon
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic pouch	Plastic bag
Package quantity	1.5 oz	1 lb
Characterizing flavor	None	None
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016498	GF1907711
Product name	TS2 Carolina Flake 8 oz	TS2 Carolina Flake
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic bag	Plastic bag
Package quantity	8 oz	1 lb
Characterizing flavor	None	None
		Predicate Tobacco Product
Product name	TS3 Mild Cavendish 1.5 oz	15 Base
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic pouch	Plastic bag
Package quantity	1.5 oz	1 lb
Characterizing flavor	None	None
		Predicate Tobacco Product
		GF1907737
Product name	TS20 Louisiana Perique 8 oz	TS20 Louisiana Perique
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic bag	Plastic bag
Package quantity	8 oz	1 lb
Characterizing flavor	None	None
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016515	GF1907739
Product name	TS23 Black Toasted Cavendish 1.5 oz	TS23 Black Toasted Cavendish
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic pouch	Plastic bag
Package quantity	1.5 oz	1 lb
Characterizing flavor	None	None

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016524	GF1907780
Product name	XK-7 Irish Crème 8 oz	XK-7 Irish Crème
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic bag	Plastic bag
Package quantity	8 oz	1 lb
Characterizing flavor	Irish Crème	Irish Crème
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016525	GF1907787
Product name	Z88 Maple Walnut 1.5 oz	Z88 Maple Walnut
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic pouch	Plastic bag
Package quantity	1.5 oz	1 lb
Characterizing flavor	Maple Walnut	Maple Walnut

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 910a4 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 910a4, 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 910a4 not included above. If you wish to discuss other ways to meet the requirements of section 910a4, submit a meeting request to us.