



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

September 10, 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: 2021.09.10 15:29:48 -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	SE0016259	GF1907985
Product name	205 Mello Peach 1.5 oz ²	205 Mello Peach
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 ounces (oz)	1 pound (lb) ³
Characterizing flavor	Peach	Peach
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016260	GF1907985
Product name	205 Mello Peach 8 oz ²	205 Mello Peach
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb
Characterizing flavor	Peach	Peach
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016261	GF1907986
Product name	206 Honey 1.5 oz ²	206 Honey
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb
Characterizing flavor	Honey	Honey
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016262	GF1907986
Product name	206 Honey 8 oz ²	206 Honey
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb
Characterizing flavor	Honey	Honey
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016263	GF1908091
Product name	245 ZBC 8 oz ²	245 ZBC
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 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	SE0016264	GF1907967
Product name	302 English 1.5 oz ²	302 Lt English
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	SE0016265	GF1907967
Product name	302 English 8 oz ²	302 Lt English
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	SE0016266	GF1907965
Product name	309 D41 Chocolate 1.5 oz ²	309 D41 Chocolate
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb
Characterizing flavor	Chocolate	Chocolate
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016267	GF1907965
Product name	309 D41 Chocolate 8 oz ²	309 D41 Chocolate
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb
Characterizing flavor	Chocolate	Chocolate
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016268	GF1907962
Product name	333 Coco Crème 8 oz ²	333 Coco Crème
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb
Characterizing flavor	Chocolate	Chocolate
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016269	GF1907959
Product name	500 African Queen 1.5 oz ²	500 African Queen
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	SE0016270	GF1907959
Product name	500 African Queen 8 oz ²	500 African Queen
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb
Characterizing flavor	Vanilla	Vanilla
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016271	GF1907945
Product name	502 Medium English 8 oz ²	502 Medium English
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	SE0016272	GF1907944
Product name	503 Heavy English 1.5 oz ²	503 Heavy English
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	SE0016273	GF1907944
Product name	503 Heavy English 8 oz ²	503 Heavy English
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	SE0016274	GF1907943
Product name	504C Aromatic English 8 oz ²	504C Aromatic English
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb
Characterizing flavor	Vanilla	Vanilla
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016275	GF1907844
Product name	512 Balkan II 1.5 oz ²	512 Balkan II
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	SE0016276	GF1907844
Product name	512 Balkan II 8 oz ²	512 Balkan II
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	SE0016277	GF1907843
Product name	513AAA 1.5 oz ²	513AAA Bulk
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	SE0016278	GF1907843
Product name	513AAA 8 oz ²	513AAA Bulk
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	SE0016279	GF1907839
Product name	516 RVL-1 1.5 oz ²	516 RVL-1
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	SE0016280	GF1907839
Product name	516 RVL-1 8 oz ²	516 RVL-1
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	SE0016281	GF1907838
Product name	517 Blackened Burley 1.5 oz ²	517 Blackened Burley
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb
Characterizing flavor	Nutmeg	Nutmeg

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016282	GF1907824
Product name	523 Voodoo Queen 1.5 oz ²	523 Voodoo Queen
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	SE0016283	GF1907824
Product name	523 Voodoo Queen 8 oz ²	523 Voodoo Queen
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	SE0016284	GF1907817
Product name	600 USA 8 oz ²	600 USA
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb
Characterizing flavor	Vanilla	Vanilla
STN	SE0016285	GF1907816
Product name	700 Golden Rum 1.5 oz ²	700 Golden Rum
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb
Characterizing flavor	Rum	Rum
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016286	GF1907689
Product name	701 Crème Brulee 1.5 oz ²	701 Crème Brulee
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb
Characterizing flavor	Vanilla Caramel	Vanilla Caramel
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016287	GF1907689
Product name	701 Crème Brulee 8 oz ²	701 Crème Brulee
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb
Characterizing flavor	Vanilla Caramel	Vanilla Caramel

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016288	GF1907816
Product name	704 Spiced Rum 1.5 oz ²	704 Golden Rum
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb
Characterizing flavor	Rum	Rum
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016289	GF1907816
Product name	704 Spiced Rum 8 oz ²	704 Golden 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	SE0016290	GF1907694
Product name	890 Raspberry Burley 1.5 oz ²	890 Raspberry Burley
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb
Characterizing flavor	Raspberry	Raspberry
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016291	GF1907856
Product name	999 Nine 1.5 oz ²	999 Nine
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	SE0016292	GF1907856
Product name	999 Nine 8 oz ²	999 Nine
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb
Characterizing flavor	Vanilla	Vanilla
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016293	GF1907857
Product name	1004 Blend 1.5 oz ²	1004 Blend
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	SE0016294	GF1907857
Product name	1004 Blend 8 oz ²	1004 Blend
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb
Characterizing flavor	Vanilla	Vanilla
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016295	GF1907863
Product name	400300 Cherry Bon Bon 1.5 oz ²	400300 Cherry Bon Bon
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb
Characterizing flavor	Cherry	Cherry
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016296	GF1907863
Product name	400300 Cherry Bon Bon 8 oz ²	400300 Cherry Bon Bon
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	SE0016297	GF1907864
Product name	400303 Black Cherry 1.5 oz ²	400303 Black 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	SE0016298	GF1907864
Product name	400303 Black Cherry 8 oz ²	400303 Black 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	SE0016299	GF1907968
Product name	400341 English Oriental 1.5 oz ²	400341 English Oriental
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	SE0016300	GF1907968
Product name	400341 English Oriental 8 oz ²	400341 English Oriental
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	SE0016301	GF1907971
Product name	400513 Aged Maduro Cavendish 1.5 oz ²	400513 Aged Maduro Cavendish
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	SE0016302	GF1907971
Product name	400513 Aged Maduro Cavendish 8 oz ²	400513 Aged Maduro Cavendish
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb
Characterizing flavor	Vanilla	Vanilla
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016303	GF1908091
Product name	400669 Black Vanilla Cavendish 8 oz ²	245 ZBC
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb
Characterizing flavor	Vanilla	Vanilla
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016304	GF1907829
Product name	Admiral's Choice Natural 8 oz ²	Super Value Natural 12 oz
Eligibility status	Not Applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	12 oz
Characterizing flavor	None	None
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016307	GF1908102
Product name	B21 Black Spice 1.5 oz ²	B21 Black Spice
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Pouch	Plastic Bag
Package quantity	1.5 oz	1 lb
Characterizing flavor	Spice	Spice

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016308	GF1908102
Product name	B21 Black Spice 8 oz ²	B21 Black Spice
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb
Characterizing flavor	Spice	Spice
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016309	GF1908124
Product name	B22 Black and Brown 8 oz ²	B22 Black and Brown Bulk
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb
Characterizing flavor	Vanilla	Vanilla
Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016310	GF1908129
Product name	B25 Dark Chocolate 8 oz ²	B25 Dark Chocolate
Eligibility status	Not applicable	Grandfathered
Package type	Plastic Bag	Plastic Bag
Package quantity	8 oz	1 lb
Characterizing flavor	Chocolate	Chocolate

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.