

Technical Project Lead (TPL) Review of SE Reports

New Products Subject of this Review	
Submission tracking numbers (STNs)	Multiple STNs, see Appendix A
Common Attributes	
Submission date	April 24, 2020
Receipt date	April 24, 2020
Applicant	Sutliff Tobacco Company LLC
Product manufacturer	Sutliff Tobacco Company LLC
Application type	Regular Product Quantity
Product category	Pipe Tobacco Products
Product subcategory	Pipe Tobacco Filler
Cross-Referenced Submissions	
All new products	None
Supporting FDA Memoranda Relied Upon in this Review	
All new products	Product Quantity Changes in Substantial Equivalence Reports (SE Reports) for Statutorily Regulated Tobacco Products (December 7, 2017)
Recommendation	
Issue Substantially Equivalent (SE) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Matthew D. Hassink -S
Date: 2021.12.20 09:04:33 -05'00'

Matthew Hassink, Ph.D.
Team Supervisor, Division of Product Science
Office of Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Matthew R. Holman -S
Date: 2021.12.20 11:51:16 -05'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

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1. BACKGROUND

1.1. NEW AND PREDICATE PRODUCTS

The applicant submitted information for the new and predicate products listed in detail in the Appendix.

1.2. REGULATORY ACTIVITY

See Appendix for products and amendments.

1.3. SCOPE OF REVIEW

This review captures all compliance, regulatory, and scientific reviews completed for the new products that are the subject of this review.

Table 1. Disciplines reviewed

Discipline	Cycle 1	
	Reviewer(s)	Review Date
Regulatory	Fiona Kiprop	12/17/2021
Environmental Science	Christy Leppanen	9/27/2021

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate products are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE reviews dated September 10, 2021, and September 13, 2021, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate products are grandfathered and, therefore, are eligible predicate products.

OCE also completed a review to determine whether the new products are in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated October 18, 2021, concludes that the new products are in compliance with the FD&C Act.

3. SCIENTIFIC REVIEW

Full scientific review was not initiated by the Office of Science (OS) because the product characteristics of the new and corresponding predicate tobacco products are identical except for the following change in product quantity and container closure system:

SE Report	New Product Quantity	Predicate Product Quantity	% Change
SE0016453, SE0016455, SE0016457, SE0016459, SE0016474, SE0016480, SE0016485, SE0016491, SE0016499, SE0016515, SE0016525	1.5 oz	1 lb ¹	↓91
SE0016454, SE0016456, SE0016468, SE0016482, SE0016484, SE0016498, SE0016512, SE0016524	8 oz	1 lb	↓50

Change in Container Closure System

SE Report	New Product	Predicate Product
SE0016453, SE0016455, SE0016457, SE0016459, SE0016474, SE0016480, SE0016485, SE0016491, SE0016499, SE0016515, SE0016525	Plastic Pouch	Plastic Bag

OS prepared memoranda² summarizing its current thinking on product quantity changes. Existing data on product quantity changes are limited and do not address the size threshold (i.e., how much of a change in product quantity) necessary to raise different questions of public health. With respect to product quantity decreases, even though some of the currently available scientific evidence is specific to tobacco products, the studies do not separate out the effect of reduced price from size on consumption or initiation. Thus, based upon the currently available science and CTP's experience in reviewing SE Reports, product quantity changes do not cause new tobacco products to raise different questions of public health. Therefore, scientific review is unnecessary.

Additionally, differences in container closure systems could potentially affect moisture content which in turn may impact microbial growth and carcinogenic tobacco specific nitrosamine (TSNA) formation over shelf life of the new products.³ The container closure systems (CCS) of the predicate tobacco products' container closure system (CCS), a bag, and corresponding new tobacco products' CCS, a pouch, are different; however, both CCSs are reported to be comprised of plastic, although no additional ingredient information is provided. The applicant did not provide any moisture content data for the new or corresponding predicate products to support this change. However, the applicant provided a certification statement that the new and corresponding predicate products differ in only product quantity and there are no changes in per weight composition, other design features, heating source, or other features. Consequently, in this particular case with the provided information, the change in container closure systems between the new and corresponding predicate products does not cause the new products to raise different questions of public health.

¹ 1 lb is equal to 16 oz

² See memorandum on product quantity changes, dated December 7, 2017, and addendum for deemed tobacco products, dated December 30, 2019.

³ Djordjevic MV, Brunnemann KD, Hoffmann D. The need for regulation of carcinogenic N-nitrosamines in oral snuff. Food Chem Toxicol. 1993;31(7):497-501

4. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on September 27, 2021. The FONSI was supported by an environmental assessment prepared by the applicant on April 24, 2020.

5. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate tobacco products are identical except for a change in product quantity and container closure system:

- 50% increase in product quantity - SE0016454, SE0016456, SE0016468, SE0016482, SE0016484, SE0016498, SE0016512, SE0016524
- 91% decrease in product quantity - SE0016453, SE0016455, SE0016457, SE0016459, SE0016474, SE0016480, SE0016485, SE0016491, SE0016499, SE0016515, SE0016525
- Change in container closure system composition from plastic bag in the predicate products to plastic pouch in the corresponding new products- SE0016453, SE0016455, SE0016457, SE0016459, SE0016474, SE0016480, SE0016485, SE0016491, SE0016499, SE0016515, SE0016525

The OS memoranda⁴ conclude that based on OS' experience and the currently available evidence, the difference in product quantity does not cause the new tobacco products to raise different questions of public health. I concur with this conclusion.

The predicate products meet statutory requirements because it was determined that they are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007).

The new products are currently in compliance with the FD&C Act. I concur with these reviews and recommend that SE order letters be issued.

FDA examined the environmental effects of finding these new products substantially equivalent and made a finding of no significant impact.

⁴ See memorandum on product quantity changes, dated December 7, 2017, and addendum for deemed tobacco products, dated December 30, 2019.

6. APPENDICES

Appendix A. New and predicate products

Common Attributes		
Submission date	April 24, 2020	
Receipt date	April 24, 2020	
Applicant	Sutliff Tobacco Company LLC	
Product manufacturer	Sutliff Tobacco Company LLC	
Product category	Pipe Tobacco Products	
Product subcategory	Pipe Tobacco Filler	
Attributes	New Product	Predicate Product
STN	SE0016453	GF1908023
Product name ⁵	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) ¹
Characterizing flavor ⁶	Cherry	Cherry
STN	SE0016454	GF1908023
Product name ⁵	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 ⁶	Cherry	Cherry
STN	SE0016455	GF1908024
Product name ⁵	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 ⁶	Mango	Mango
STN	SE0016456	GF1908024
Product name ⁵	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 ⁶	Mango	Mango

⁵ Brand/sub-brand or other commercial name used in commercial distribution

⁶ As provided by the applicant's certification statement. For product quantity change SE Reports, FDA does not conduct substantive scientific review to evaluate the information contained in the applicant's certification statement.

STN	SE0016457	GF1908025
Product name ⁵	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 ⁶	Vanilla	Vanilla
STN	SE0016459	GF1908026
Product name ⁵	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 ⁶	Vanilla	Vanilla
STN	SE0016468	GF1908036
Product name ⁵	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 ⁶	None	None
STN	SE0016474	GF1908050
Product name ⁵	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 ⁶	None	None
STN	SE0016480	GF1908055
Product name ⁵	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 ⁶	None	None
STN	SE0016482	GF1908056
Product name ⁵	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 ⁶	Rum	Rum
STN	SE0016484	GF1908058
Product name ⁵	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 ⁶	Strawberry	Strawberry

STN	SE0016485	GF1908059
Product name ⁵	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 ⁶	Amaretto	Amaretto
STN	SE0016491	GF1907709
Product name ⁵	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 ⁶	None	None
STN	SE0016498	GF1907711
Product name ⁵	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 ⁶	None	None
STN	SE0016499	GF1907674
Product name ⁵	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 ⁶	None	None
STN	SE0016512	GF1907737
Product name ⁵	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 ⁶	None	None
STN	SE0016515	GF1907739
Product name ⁵	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 ⁶	None	None
STN	SE0016524	GF1907780
Product name ⁵	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 ⁶	Irish Crème	Irish Crème

STN	SE0016525	GF1907787
Product name ⁵	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 ⁶	Maple Walnut	Maple Walnut

Appendix B. Amendments

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Brief Description
September 11, 2020	September 11, 2020	SE0019556	All	Yes	Response to August 18, 2020 Environmental Information Request
November 09, 2020	November 09, 2020	SE0023364	All	No, Administrative Update	Response to August 18, 2020 Environmental Information Request
August 19, 2021	August 19, 2021	SE0024835	SE0016491	Yes	Correction or clarification to the original submission.
August 19, 2021	August 19, 2021	SE0024836	SE0016491	No, Administrative Update	Correction or clarification to the original submission.