

Technical Project Lead (TPL) Review: SE0016259 – SE0016283

Common Attributes of SE Reports	
Date of Submission:	April 22, 2020
Date of Receipt:	April 22, 2020
Applicant:	Sutliff Tobacco Company LLC
Product Category:	Pipe Tobacco Products
Product Sub-Category:	Pipe Tobacco Filler
Report Type	Product Quantity Change Regular

	New Tobacco Product Specific Attributes	Predicate Tobacco Product Specific Attributes
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016259 205 Mellow Peach 1.5 oz Plastic Pouch 1.5 ounces (oz) Peach N/A	GF1907985 205 Mellow Peach Plastic Bag 1 pound (lb) ¹ Peach Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016260 205 Mellow Peach 8 oz Plastic bag 8 oz Peach N/A	GF1907985 205 Mellow Peach Plastic bag 1 lb Peach Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016261 206 Honey 1.5 oz Plastic pouch 1.5 oz Honey N/A	GF1907986 206 Honey Plastic bag 1 lb Honey Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016262 206 Honey 8 oz Plastic bag 8 oz Honey N/A	GF1907986 206 Honey Plastic bag 1 lb Honey Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016263 245 ZBC 8 oz Plastic bag 8 oz Vanilla N/A	GF1908091 245 ZBC Plastic bag 1 lb Vanilla Grandfathered

¹ One pound is equal to 16 ounces

² 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.

	New Tobacco Product Specific Attributes	Predicate Tobacco Product Specific Attributes
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016264 302 English 1.5 oz Plastic pouch 1.5 oz None N/A	GF1907967 302 Lt English Plastic bag 1 lb None Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016265 302 English 8 oz Plastic bag 8 oz None N/A	GF1907967 302 Lt English Plastic bag 1 lb None Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016266 309 D41 Chocolate 1.5 oz Plastic pouch 1.5 oz Chocolate N/A	GF1907965 309 D41 Chocolate Plastic bag 1 lb Chocolate Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016267 309 D41 Chocolate 8 oz Plastic bag 8 oz Chocolate N/A	GF1907965 309 D41 Chocolate Plastic bag 1 lb Chocolate Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016268 333 Coco Crème 8 oz Plastic bag 8 oz Chocolate N/A	GF1907962 333 Coco Crème Plastic bag 1 lb Chocolate Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016269 500 African Queen 1.5 oz Plastic pouch 1.5 oz Vanilla N/A	GF1907959 500 African Queen Plastic bag 1 lb Vanilla Grandfathered

	New Tobacco Product Specific Attributes	Predicate Tobacco Product Specific Attributes
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016270 500 African Queen 8 oz Plastic bag 8 oz Vanilla N/A	GF1907959 500 African Queen Plastic bag 1 lb Vanilla Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016271 502 Medium English 8 oz Plastic bag 8 oz None N/A	GF1907945 502 Medium English Plastic bag 1 lb None Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016272 503 Heavy English 1.5 oz Plastic pouch 1.5 oz None N/A	GF1907944 503 Heavy English Plastic bag 1 lb None Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016273 503 Heavy English 8 oz Plastic bag 8 oz None N/A	GF1907944 503 Heavy English Plastic bag 1 lb None Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016274 504C Aromatic English 8 oz Plastic bag 8 oz Vanilla N/A	GF1907943 504C Aromatic English Plastic bag 1 lb Vanilla Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016275 512 Balkan II 1.5 oz Plastic pouch 1.5 oz None N/A	GF1907844 512 Balkan II Plastic bag 1 lb None Grandfathered

	New Tobacco Product Specific Attributes	Predicate Tobacco Product Specific Attributes
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016276 512 Balkan II 8 oz Plastic bag 8 oz None N/A	GF1907844 512 Balkan II Plastic bag 1 lb None Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016277 513AAA 1.5 oz Plastic pouch 1.5 oz None N/A	GF1907843 513AAA Bulk Plastic bag 1 lb None Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016278 513AAA 8 oz Plastic bag 8 oz None N/A	GF1907843 513AAA Bulk Plastic bag 1 lb None Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016279 516 RVL-1 1.5 oz Plastic pouch 1.5 oz None N/A	GF1907839 516 RVL-1 Plastic bag 1 lb None Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016280 516 RVL-1 8 oz Plastic bag 8 oz None N/A	GF1907839 516 RVL-1 Plastic bag 1 lb None Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016281 517 Blackened Burley 1.5 oz Plastic pouch 1.5 oz Spice N/A	GF1907838 517 Blackened Burley Plastic bag 1 lb Spice Grandfathered

	New Tobacco Product Specific Attributes	Predicate Tobacco Product Specific Attributes
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status:	SE0016282 523 Voodoo Queen 1.5 oz Plastic pouch 1.5 oz None N/A	GF1907824 523 Voodoo Queen Plastic bag 1 lb None Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status:	SE0016283 523 Voodoo Queen 8 oz Plastic bag 8 oz None N/A	GF1907824 523 Voodoo Queen Plastic bag 1 lb None Grandfathered
Recommendation		
Issue Substantially Equivalent (SE) orders.		

Technical Project Lead (TPL):

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Date: 2020.09.02 17:26:29 -04'00'

Cristi Stark, M.S.
Director
Division of Regulatory Project Management
Office of Science

Signatory Decision:

- Concur with TPL recommendation and basis of recommendation
- Concur with TPL recommendation with additional comments (see separate memo)
- Do not concur with TPL recommendation (see separate memo)

Digitally signed by Matthew R. Holman -S
Date: 2020.09.03 09:11:57 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND 9

 1.1. REGULATORY ACTIVITY RELATED TO THIS REVIEW 9

 1.2. SCOPE OF REVIEW 9

2. REGULATORY REVIEW 9

3. COMPLIANCE REVIEW 10

4. SCIENTIFIC REVIEW 10

5. ENVIRONMENTAL DECISION 11

6. CONCLUSION AND RECOMMENDATION..... 11

1. BACKGROUND

1.1. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On April 22, 2020, FDA received 25 Product Quantity Change SE Reports from Sutliff Tobacco Company LLC. On May 20, 2020, FDA issued Acceptance letters to the applicant. FDA’s Office of Compliance and Enforcement (OCE) contacted the applicant on May 27, 2020, to request additional information to complete predicate eligibility review for SE0016264, SE0016265, SE0016277, SE0016278 and SE0016281. FDA received the applicant’s response to OCE’s request on May 28, 2020 (SE0016630).

Product Name	SE Report	Amendments
205 Mellow Peach 1.5 oz	SE0016259	N/A
205 Mellow Peach 8 oz	SE0016260	
206 Honey 1.5 oz	SE0016261	
206 Honey 8 oz	SE0016262	
245 ZBC 8 oz	SE0016263	
302 English 1.5 oz	SE0016264	SE0016630
302 English 8 oz	SE0016265	N/A
309 D41 Chocolate 1.5 oz	SE0016266	
309 D41 Chocolate 8 oz	SE0016267	
333 Coco Crème 8 oz	SE0016268	
500 African Queen 1.5 oz	SE0016269	
500 African Queen 8 oz	SE0016270	
502 Medium English 8 oz	SE0016271	
503 Heavy English 1.5 oz	SE0016272	
503 Heavy English 8 oz	SE0016273	
504C Aromatic English 8 oz	SE0016274	
512 Balkan II 1.5 oz	SE0016275	
512 Balkan II 8 oz	SE0016276	SE0016630
513AAA 1.5 oz	SE0016277	
513AAA 8 oz	SE0016278	N/A
516 RVL-1 1.5 oz	SE0016279	
516 RVL-1 8 oz	SE0016280	SE0016630
517 Blackened Burley 1.5 oz	SE0016281	
523 Voodoo Queen 1.5 oz	SE0016282	N/A
523 Voodoo Queen 8 oz	SE0016283	

1.2. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these SE Reports.

2. REGULATORY REVIEW

Acceptance reviews were completed by Ester Hatton on May 20, 2020.

Regulatory reviews were completed by Ryan Nguy on September 1, 2020. The regulatory reviews conclude that the SE Reports contain acceptable certification statements which do not require additional data to be submitted.

3. COMPLIANCE REVIEW

OCE completed reviews to determine whether the applicant established that the predicate tobacco products are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE reviews dated June 8, 2020 (for SE0016262), June 9, 2020 (for SE0016263 – SE0016265 and SE0016268 – SE0016281), June 11, 2020 (for SE0016266, SE0016267, SE0016282, and SE0016283), July 27, 2020 (for SE0016261), and July 29, 2020 (for SE0016259 and SE0016260), conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered and, therefore, are eligible predicate tobacco products.

OCE also completed a review to determine whether the new tobacco 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 July 30, 2020, concludes that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

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:

SE Report	New Tobacco Product Quantity	Predicate Tobacco Product Quantity	% Change
SE0016259, SE0016261, SE0016264, SE0016266, SE0016269, SE0016272, SE0016275, SE0016277, SE0016279, SE0016281, SE0016282	1.5 oz	1 lb ¹	↓91
SE0016260, SE0016262, SE0016263, SE0016265, SE0016267, SE0016268, SE0016270, SE0016271, SE0016273, SE0016274, SE0016276, SE0016278, SE0016280, SE0016283	8 oz	1 lb ¹	↓50

OS prepared memoranda³ 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

³ See memorandum on product quantity changes, dated December 7, 2017, and addendum for deemed tobacco products, dated December 30, 2019.

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.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Shannon Hanna on August 6, 2020.

The environmental review found the following issues:

1. The submitted environmental assessments (EAs) cannot be confidential and are required to be public documents.
2. The applicant did not provide market volume information for the predicate tobacco products and did not provide current market volume information or fifth-year market volume estimates for the new tobacco products.
3. The submitted EAs lack the name and position of the preparer and a signed certification statement.

The environmental review found that the submitted EA does not provide enough information for an EA as required in 21 CFR 25.40. Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI).

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate tobacco products are identical except for the following change in product quantity:

- 91% decrease (1 lb [16 oz] to 1.5 oz) – SE0016259, SE0016261, SE0016264, SE0016266, SE0016269, SE0016272, SE0016275, SE0016277, SE0016279, SE0016281, SE0016282
- 50% decrease (1 lb [16 oz] to 8 oz) – SE0016260, SE0016262, SE0016263, SE0016265, SE0016267, SE0016268, SE0016270, SE0016271, SE0016273, SE0016274, SE0016276, SE0016278, SE0016280, SE0016283

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 tobacco 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 tobacco products are currently in compliance with the FD&C Act.

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

FDA examined the environmental effects of finding the new tobacco products substantially equivalent and found additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing SE orders.

An Environmental Information Request letter should be issued to the applicant requesting the following information:

1. Your submitted environmental assessments (EAs) lack current market volume of the new and predicate tobacco products, the first- and fifth-year market volume projections for the predicate tobacco products, and the fifth-year market volume projections for the new tobacco products. In your revised EAs, provide this market volume information in number of units. This information is used to assess the environmental impacts of manufacturing, use, and disposal of the new tobacco products.

In addition, while alternative formats may be used, the following changes to your EA would assist in the completeness of the EA and promote efficiency in the review process:

2. Your submitted EAs are marked confidential; however, the EA is a public document. 21 CFR 25.51 (a) states that “Data and information that are protected from disclosure by 18 U.S.C. 1905 or 21 U.S.C. 331(j) or 360j(c) shall not be included in the portion of environmental documents that is made public. When such data and information are pertinent to the environmental review of a proposed action, an applicant or petitioner shall submit such data and information separately in a confidential section and shall summarize the confidential data and information in the EA to the extent possible.” Your submitted EAs contain language which states “FOIA Exempt 5 U.S.C §552(b)(4)” and “Please note that the attached contains confidential commercial and non-public information. All such confidential commercial information is exempt from public disclosure under § 301(j) and § 906(c) of the F.D.C.A, 5 U.S.C. § 552(b)(4), 18 U.S.C. § 1905 and 21 C.F.R. § 20.61. Sutliff requests that FDA maintain the confidentiality of this information.” This language is not consistent with 21 CFR 25.21(a). Submit revised EAs that are not confidential and summarize confidential data and information to the extent possible in accordance with 21 CFR 25.51(a). One way to address this is to include the detailed confidential information in a confidential appendix.
3. Your submitted EAs lack the name and position of the person(s) who prepared the EAs and a signed certification statement. In each revised EA, include the name and position of the person or persons who prepared the EA and a certification that contains a signed and dated statement as follows:

"The undersigned official, on behalf of [insert company name], certifies that the information presented is true, accurate, and complete.

(Date)

(Signature of responsible official)

(Name and title of responsible official, printed)"

If the applicant adequately responds to the request and an EIS or FONSI is completed, SE order letters should be issued for the new tobacco products in SE0016259 – SE0016283, as identified on the cover page of this review.