

Technical Project Lead (TPL) Review: SE0016284 – SE0016304 and SE0016307 – SE0016310

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:	SE0016284 600 USA 8 oz Plastic Bag 8 ounces (oz) Vanilla N/A	GF1907817 600 USA Plastic Bag 1 pound (lb) ¹ Vanilla Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016285 700 Golden Rum 1.5 oz Plastic Pouch 1.5 oz Rum N/A	GF1907816 700 Golden Rum Plastic Bag 1 lb Rum Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016286 701 Crème Brulee 1.5 oz Plastic Pouch 1.5 oz Vanilla Caramel N/A	GF1907689 701 Crème Brulee Plastic Bag 1 lb Vanilla Caramel Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016287 701 Crème Brulee 8 oz Plastic Bag 8 oz Vanilla Caramel N/A	GF1907689 701 Crème Brulee Plastic Bag 1 lb Vanilla Caramel Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status:	SE0016288 704 Spiced Rum 1.5 oz Plastic Pouch 1.5 oz Rum N/A	GF1907816 700 Golden Rum Plastic Bag 1 lb Rum 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:	SE0016289 704 Spiced Rum 8 oz Plastic Bag 8 oz Rum N/A	GF1907816 700 Golden Rum Plastic Bag 1 lb Rum Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status:	SE0016290 890 Raspberry Burley 1.5 oz Plastic Pouch 1.5 oz Raspberry N/A	GF1907694 890 Raspberry Burley Plastic Bag 1 lb Raspberry Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status:	SE0016291 999 Nine 1.5 oz Plastic Pouch 1.5 oz Vanilla N/A	GF1907856 999 Nine Plastic Bag 1 lb Vanilla Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status:	SE0016292 999 Nine 8 oz Plastic Bag 8 oz Vanilla N/A	GF1907856 999 Nine Plastic Bag 1 lb Vanilla Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status:	SE0016293 1004 Blend 1.5 oz Plastic Pouch 1.5 oz Vanilla N/A	GF1907857 1004 Blend Plastic Bag 1 lb Vanilla Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status:	SE0016294 1004 Blend 8 oz Plastic Bag 8 oz Vanilla N/A	GF1907857 1004 Blend 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:	SE0016295 400300 Cherry Bon Bon 1.5 oz Plastic Pouch 1.5 oz Cherry N/A	GF1907863 Cherry Bon Bon Plastic Bag 1 lb Cherry Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status:	SE0016296 400300 Cherry Bon Bon 8 oz Plastic Bag 8 oz Cherry N/A	GF1907863 Cherry Bon Bon Plastic Bag 1 lb Cherry Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status:	SE0016297 400303 Black Cherry 1.5 oz Plastic Pouch 1.5 oz Cherry N/A	GF1907864 400303 Black Cherry Plastic Bag 1 lb Cherry Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status:	SE0016298 Black Cherry 8 oz Plastic Bag 8 oz Cherry N/A	GF1907864 400303 Black Cherry Plastic Bag 1 lb Cherry Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status:	SE0016299 400341 English Oriental 1.5 oz Plastic Pouch 1.5 oz None N/A	GF1907968 400341 English Oriental Plastic Bag 1 lb None Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status:	SE0016300 400341 English Oriental 8 oz Plastic Bag 8 oz None N/A	GF1907968 400341 English Oriental 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:	SE0016301 400513 Aged Maduro Cavendish 1.5 oz Plastic Pouch 1.5 oz Vanilla N/A	GF1907971 400513 Aged Maduro Cavendish Plastic Bag 1 lb Vanilla Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status:	SE0016302 400513 Aged Maduro Cavendish 8 oz Plastic Bag 8 oz Vanilla N/A	GF1907971 400513 Aged Maduro Cavendish Plastic Bag 1 lb Vanilla Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status:	SE0016303 400669 Black Vanilla 8 oz Plastic Bag 8 oz Vanilla N/A	GF1908091 245 ZBC Plastic Bag 1 lb Vanilla Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status:	SE0016304 Admiral's Choice Natural 8 oz Plastic Bag 8 oz None N/A	GF1907829 Super Value Natural 12 oz Plastic Bag 12 oz None Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status:	SE0016307 B21 Black Spice 1.5 oz Plastic Pouch 1.5 oz Spice N/A	GF1908102 B21 Black Spice Plastic Bag 1 lb Spice Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status:	SE0016308 B21 Black Spice 8 oz Plastic Bag 8 oz Spice N/A	GF1908102 B21 Black Spice 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:	SE0016309 B22 Black and Brown 8 oz Plastic Bag 8 oz Vanilla N/A	GF1908124 B22 Black and Brown Bulk Plastic Bag 1 lb Vanilla Grandfathered
Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status:	SE0016310 B25 Dark Chocolate 8 oz Plastic Bag 8 oz Chocolate N/A	GF1908129 B25 Dark Chocolate Plastic Bag 1 lb Chocolate Grandfathered
Recommendation		
Issue Substantially Equivalent (SE) orders.		

Technical Project Lead (TPL):

Digitally signed by Lana M. Rossiter -S
Date: 2020.10.21 15:11:13 -04'00'

Lana M. Rossiter, Ph.D.
Commander, USPHS
Chief, Regulatory Project Management Branch IV
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 Deirdre L. Kittner -S
Date: 2020.10.21 15:18:48 -04'00'

Deirdre Kittner, Ph.D.
Deputy Director for Regulatory
Science
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 10

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 an Acceptance letter to the applicant for SE0016284 – SE0016304 and SE0016307 – SE0016310. FDA’s Office of Compliance and Enforcement (OCE) contacted the applicant on July 24, 2020, to request additional information to complete predicate eligibility review for SE0016309. FDA received the applicant’s response to OCE’s request on July 24, 2020 (SE0016893).

Product Name	SE Report	Amendment	
600 USA 8 oz	SE0016284	N/A	
700 Golden Rum 1.5 oz	SE0016285		
701 Crème Brulee 1.5 oz	SE0016286		
701 Crème Brulee 8 oz	SE0016287		
704 Spiced Rum 1.5 oz	SE0016288		
704 Spiced Rum 8 oz	SE0016289		
890 Raspberry Burley 1.5 oz	SE0016290		
999 Nine 1.5 oz	SE0016291		
999 Nine 8 oz	SE0016292		
1004 Blend 1.5 oz	SE0016293		
1004 Blend 8 oz	SE0016294		
400300 Cherry Bon Bon 1.5 oz	SE0016295		
400300 Cherry Bon Bon 8 oz	SE0016296		
400303 Black Cherry 1.5 oz	SE0016297		
400303 Black Cherry 8 oz	SE0016298		
400341 English Oriental 1.5 oz	SE0016299		
400341 English Oriental 8 oz	SE0016300		
400513 Aged Maduro Cavendish 1.5 oz	SE0016301		
400513 Aged Maduro Cavendish 8 oz	SE0016302		
400669 Black Vanilla 8 oz	SE0016303		
Admiral's Choice Natural 8 oz	SE0016304		
B21 Black Spice 1.5 oz	SE0016307		
B21 Black Spice 8 oz	SE0016308		
B22 Black and Brown 8 oz	SE0016309		SE0016893
B25 Dark Chocolate 8 oz	SE0016310		N/A

1.2. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

An acceptance review was completed by Ester Hatton on May 20, 2020.

A Regulatory review was completed by Iqra Javaid on October 21, 2020. The regulatory review concludes that the SE Reports contain acceptable certification statements which do not require additional data to be submitted.

3. COMPLIANCE REVIEW

The 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 9, 2020 (for SE0016284 – SE0016289), July 27, 2020 (for SE0016301 – SE0016302), July 28, 2020 (for SE0016307 – SE0016308), July 29, 2020 (for SE0016295 – SE0016296), August 3, 2020 (for SE0016297 – SE0016298, and SE0016304), August 4, 2020 (for SE0016290 – SE0016294, SE0016299 – SE0016300, SE0016303, and SE0016310), and August 7, 2020 (for SE0016309), 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 reviews dated September 9, 2020 and October 13, 2020, conclude 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
SE0016285 – SE0016286, SE0016288, SE0016290, SE0016291, SE0016293, SE0016295, SE0016297, SE0016299, SE0016301, SE0016307	1.5 oz	1 lb ¹	↓91
SE0016284, SE0016287, SE0016289, SE0016292, SE0016294, SE0016296, SE0016298, SE0016300, SE0016302 – SE0016303, SE0016308 – SE0016310	8 oz	1 lb ¹	↓50
SE0016304	8 oz	12 oz	↓33

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 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 Yasmin Termeh-Zonoozi on September 1, 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) – SE0016285 – 286, SE0016288, SE0016290, SE0016291, SE0016293, SE0012695, SE0016297, SE0016299, SE0016301, SE0016307
- 50% decrease (1 lb [16 oz] to 8 oz) – SE0016284, SE0016287, SE0016289, SE0016292, SE0016294, SE0016296, SE0016298, SE0016300, SE0016302 – 303, SE0016308 – 310
- 33% decrease (12 oz to 8 oz) – SE0016304

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

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.

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.

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

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 SE0016284 – SE0016304 and SE0016307 – SE0016310, as identified on the cover page of this review.