

## Technical Project Lead (TPL) Review: SE0016218 and SE0016235 – SE0016258

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

	<b>New Tobacco Product Specific Attributes</b>	<b>Predicate Tobacco Product Specific Attributes</b>
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:</b> <sup>2</sup> <b>Eligibility Status:</b>	SE0016218  600 USA 1.5 oz Plastic Pouch 1.5 ounces (oz) Vanilla N/A	GF1907817  600 USA Plastic Bag 1 pound (lb) <sup>1</sup> Vanilla Grandfathered
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:</b> <sup>2</sup> <b>Eligibility Status:</b>	SE0016235  10 Natural Cavendish 8 oz Plastic bag 8 oz None N/A	GF1907669  10 Natural Cavendish Plastic bag 1 lb None Grandfathered
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:</b> <sup>2</sup> <b>Eligibility Status:</b>	SE0016236  11 Whiskey Cavendish 1.5 oz Plastic pouch 1.5 oz Whiskey N/A	GF1907670  11 Whiskey Cavendish Plastic bag 1 lb Whiskey Grandfathered
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:</b> <sup>2</sup> <b>Eligibility Status:</b>	SE0016237  11 Whiskey Cavendish 8 oz Plastic bag 8 oz Whiskey N/A	GF1907670  11 Whiskey Cavendish Plastic bag 1 lb Whiskey Grandfathered
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:</b> <sup>2</sup> <b>Eligibility Status:</b>	SE0016238  12 Cherry Cavendish 8 oz Plastic bag 8 oz Cherry N/A	GF1907671  12 Cherry Cavendish Plastic bag 1 lb Cherry Grandfathered

<sup>1</sup> One pound is equal to 16 ounces

<sup>2</sup> 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.

	<b>New Tobacco Product Specific Attributes</b>	<b>Predicate Tobacco Product Specific Attributes</b>
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:</b> <sup>2</sup> <b>Eligibility Status:</b>	SE0016239  13 Tropic Cavendish 1.5 oz Plastic pouch 1.5 oz Mango N/A	GF1907672  13 Tropic Cavendish Plastic bag 1 lb Mango Grandfathered
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:</b> <sup>2</sup> <b>Eligibility Status:</b>	SE0016240  13 Tropic Cavendish 8 oz Plastic bag 8 oz Mango N/A	GF1907672  13 Tropic Cavendish Plastic bag 1 lb Mango Grandfathered
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:</b> <sup>2</sup> <b>Eligibility Status:</b>	SE0016241  14 Maple Cavendish 8 oz Plastic bag 8 oz Maple N/A	GF1907673  14 Maple Cavendish Plastic bag 1 lb Maple Grandfathered
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:</b> <sup>2</sup> <b>Eligibility Status:</b>	SE0016242  16 English Toffee 1.5 oz Plastic pouch 1.5 oz Toffee N/A	GF1907675  16 English Toffee Plastic bag 1 lb Toffee Grandfathered
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:</b> <sup>2</sup> <b>Eligibility Status:</b>	SE0016243  18 Mellow 1.5 oz Plastic pouch 1.5 oz Hazelnut N/A	GF1908274  QFC Mellow N Mild 16 oz Plastic bag 1 lb Hazelnut Grandfathered
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:</b> <sup>2</sup> <b>Eligibility Status:</b>	SE0016244  18 Mellow 8 oz Plastic bag 8 oz Hazelnut N/A	GF1908274  QFC Mellow N Mild 16 oz Plastic bag 1 lb Hazelnut Grandfathered

	<b>New Tobacco Product Specific Attributes</b>	<b>Predicate Tobacco Product Specific Attributes</b>
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:<sup>2</sup></b> <b>Eligibility Status:</b>	SE0016245  64K Embassy 1.5 oz Plastic pouch 1.5 oz Vanilla N/A	GF1907846  64K Embassy Plastic bag 1 lb Vanilla Grandfathered
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:<sup>2</sup></b> <b>Eligibility Status:</b>	SE0016246  101 Black Kathy 1.5 oz Plastic pouch 1.5 oz Spice N/A	GF1907849  101 Black Kathy Plastic bag 1 lb Spice Grandfathered
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:<sup>2</sup></b> <b>Eligibility Status:</b>	SE0016247  103 Whiskey Galore 1.5 oz Plastic pouch 1.5 oz Whiskey N/A	GF1907851  103 Whiskey Galore Plastic bag 1 lb Whiskey Grandfathered
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:<sup>2</sup></b> <b>Eligibility Status:</b>	SE0016248  103 Whiskey Galore 8 oz Plastic bag 8 oz Whiskey N/A	GF1907851  103 Whiskey Galore Plastic bag 1 lb Whiskey Grandfathered
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:<sup>2</sup></b> <b>Eligibility Status:</b>	SE0016249  105 Royal Viking 1.5 oz Plastic pouch 1.5 oz Vanilla N/A	GF1907852  105 Royal Viking Plastic bag 1 lb Vanilla Grandfathered
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:<sup>2</sup></b> <b>Eligibility Status:</b>	SE0016250  111 Blue Grass 1.5 oz Plastic pouch 1.5 oz Vanilla N/A	GF1907853  111 Blue Grass Plastic bag 1 lb Vanilla Grandfathered

	<b>New Tobacco Product Specific Attributes</b>	<b>Predicate Tobacco Product Specific Attributes</b>
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:<sup>2</sup></b> <b>Eligibility Status:</b>	SE0016251  111 Blue Grass 8 oz Plastic bag 8 oz Vanilla N/A	GF1907853  111 Blue Grass Plastic bag 1 lb Vanilla Grandfathered
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:<sup>2</sup></b> <b>Eligibility Status:</b>	SE0016252  131 Vanilla Maple 1.5 oz Plastic pouch 1.5 oz Vanilla Maple N/A	GF1907855  131 Vanilla Maple Plastic bag 1 lb Vanilla Maple Grandfathered
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:<sup>2</sup></b> <b>Eligibility Status:</b>	SE0016253  131 Vanilla Maple 8 oz Plastic bag 8 oz Vanilla Maple N/A	GF1907855  131 Vanilla Maple Plastic bag 1 lb Vanilla Maple Grandfathered
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:<sup>2</sup></b> <b>Eligibility Status:</b>	SE0016254  200 Red Wine 1.5 oz Plastic pouch 1.5 oz Red Wine N/A	GF1907981  200 Red Wine Plastic bag 1 lb Red Wine Grandfathered
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:<sup>2</sup></b> <b>Eligibility Status:</b>	SE0016255  201 Sangria 1.5 oz Plastic pouch 1.5 oz Sangria N/A	GF1907982  201 Sangria Plastic bag 1 lb Sangria Grandfathered
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:<sup>2</sup></b> <b>Eligibility Status:</b>	SE0016256  201 Sangria 8 oz Plastic bag 8 oz Sangria N/A	GF1907982  201 Sangria Plastic bag 1 lb Sangria Grandfathered

	<b>New Tobacco Product Specific Attributes</b>	<b>Predicate Tobacco Product Specific Attributes</b>
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:<sup>2</sup></b> <b>Eligibility Status:</b>	SE0016257  203 Coffee 1.5 oz Plastic pouch 1.5 oz Coffee N/A	GF1907983  203 Coffee Plastic bag 1 lb Coffee Grandfathered
<b>Submission Tracking Number:</b> <b>Product Name:</b> <b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:<sup>2</sup></b> <b>Eligibility Status:</b>	SE0016258  203 Coffee 8 oz Plastic bag 8 oz Coffee N/A	GF1907983  203 Coffee Plastic bag 1 lb Coffee Grandfathered
<b>Recommendation</b>		
<b>Issue Substantially Equivalent (SE) orders.</b>		

**Technical Project Lead (TPL):**

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Date: 2020.08.17 17:33:48 -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: 2020.08.17 19:39:55 -04'00'

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

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**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. On May 20, 2020, FDA issued Acceptance letters to the applicant. FDA’s Office of Compliance and Enforcement (OCE) contacted the applicant on June 24, 2020, to request additional information to complete predicate eligibility review for SE0016242 and SE0016246. FDA received the applicant’s response to OCE’s request on June 30, 2020 (SE0016757).

Product Name	SE Report	Amendments
600 USA 1.5 oz	SE0016218	N/A
10 Natural Cavendish 8 oz	SE0016235	
11 Whiskey Cavendish 1.5 oz	SE0016236	
12 Cherry Cavendish 8 oz	SE0016238	
13 Tropic Cavendish 1.5 oz	SE0016239	
13 Tropic Cavendish 8 oz	SE0016240	
14 Maple Cavendish 8 oz	SE0016241	
16 English Toffee 1.5 oz	SE0016242	SE0016757
18 Mellow 1.5 oz	SE0016243	N/A
18 Mellow 8 oz	SE0016244	
64K Embassy 1.5 oz	SE0016245	
101 Black Kathy 1.5 oz	SE0016246	SE0016757
103 Whiskey Galore 1.5 oz	SE0016247	N/A
103 Whiskey Galore 8 oz	SE0016248	
105 Royal Viking 1.5 oz	SE0016249	
111 Blue Grass 1.5 oz	SE0016250	
111 Blue Grass 8 oz	SE0016251	
131 Vanilla Maple 1.5 oz	SE0016252	
131 Vanilla Maple 8 oz	SE0016253	
200 Red Wine 1.5 oz	SE0016254	
201 Sangria 1.5 oz	SE0016255	
201 Sangria 8 oz	SE0016256	
203 Coffee 1.5 oz	SE0016257	
203 Coffee 8 oz	SE0016258	

**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 Jessica Kiser on August 10, 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 other than exclusively in test markets as of February 15, 2007). The OCE reviews dated July 9, 2020 (for SE0016236-SE0016241, SE0016243-SE0016253, and SE0016255-SE0016258), July 10, 2020 (for SE0016218, SE0016235, and SE0016254), and July 11, 2020 (for SE0016242), 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 16, 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
SE0016218, SE0016236, SE0016239, SE0016242, SE0016243, SE0016245, SE0012646, SE0016247, SE0016249, SE0016250, SE0016252, SE0016254, SE0016255, SE001627	1.5 oz	1 lb <sup>1</sup>	↓ 91
SE0016235, SE0016237, SE0016238, SE0016240, SE0016241, SE0016244, SE0016248, SE0016251, SE0016253, SE0016256, SE0016258	8 oz	1 lb <sup>1</sup>	↓ 50

OS prepared memoranda<sup>3</sup> 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

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

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 July 28, 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) – SE0016218, SE0016236, SE0016239, SE0016242, SE0016243, SE0016245, SE0012646, SE0016247, SE0016249, SE0016250, SE0016252, SE0016254, SE0016255, SE001627
- 50% decrease (1 lb [16 oz] to 8 oz) – SE0016235, SE0016237, SE0016238, SE0016240, SE0016241, SE0016244, SE0016248, SE0016251, SE0016253, SE0016256, SE0016258

The OS memoranda<sup>4</sup> 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 other than exclusively in test markets as of February 15, 2007).

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

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<sup>4</sup> 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 SE0016218 and SE0016235 - SE0016258, as identified on the cover page of this review.