

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

| 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: | 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 |
| Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status: | SE0016240 13 Tropic Cavendish 8 oz Plastic bag 8 oz Mango N/A | GF1907672 13 Tropic Cavendish Plastic bag 1 lb Mango Grandfathered |
| Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status: | SE0016241 14 Maple Cavendish 8 oz Plastic bag 8 oz Maple N/A | GF1907673 14 Maple Cavendish Plastic bag 1 lb Maple Grandfathered |
| Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status: | 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 |
| Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status: | 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 |
| Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor: ² Eligibility Status: | 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 |

| | New Tobacco Product Specific Attributes | Predicate Tobacco Product Specific Attributes |
|---|---|--|
| Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status: | SE0016245 64K Embassy 1.5 oz Plastic pouch 1.5 oz Vanilla N/A | GF1907846 64K Embassy Plastic bag 1 lb Vanilla Grandfathered |
| Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status: | 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 |
| Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status: | 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 |
| Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status: | SE0016248 103 Whiskey Galore 8 oz Plastic bag 8 oz Whiskey N/A | GF1907851 103 Whiskey Galore Plastic bag 1 lb Whiskey Grandfathered |
| Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status: | 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 |
| Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status: | 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 |

| | New Tobacco Product Specific Attributes | Predicate Tobacco Product Specific Attributes |
|---|--|---|
| Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status: | SE0016251 111 Blue Grass 8 oz Plastic bag 8 oz Vanilla N/A | GF1907853 111 Blue Grass Plastic bag 1 lb Vanilla Grandfathered |
| Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status: | 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 |
| Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status: | 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 |
| Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status: | 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 |
| Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status: | SE0016255 201 Sangria 1.5 oz Plastic pouch 1.5 oz Sangria N/A | GF1907982 201 Sangria Plastic bag 1 lb Sangria Grandfathered |
| Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status: | SE0016256 201 Sangria 8 oz Plastic bag 8 oz Sangria N/A | GF1907982 201 Sangria Plastic bag 1 lb Sangria 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: | SE0016257 203 Coffee 1.5 oz Plastic pouch 1.5 oz Coffee N/A | GF1907983 203 Coffee Plastic bag 1 lb Coffee Grandfathered |
| Submission Tracking Number: Product Name: Package Type: Package Quantity: Characterizing Flavor:² Eligibility Status: | SE0016258 203 Coffee 8 oz Plastic bag 8 oz Coffee N/A | GF1907983 203 Coffee Plastic bag 1 lb Coffee Grandfathered |
| Recommendation | | |
| Issue Substantially Equivalent (SE) orders. | | |

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 | SE0016757 |
| 101 Black Kathy 1.5 oz | SE0016246 | |
| 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 ¹ | ↓91 |
| SE0016235, SE0016237, SE0016238, SE0016240, SE0016241, SE0016244, SE0016248, SE0016251, SE0016253, SE0016256, SE0016258 | 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 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

³ 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, SE0016246, 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 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 other than exclusively in test markets 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 SE0016218 and SE0016235 - SE0016258, as identified on the cover page of this review.