Technical Project Lead (TPL) Review: SE0015538

SE0015538: Big Duke Sweet Blend (16 oz.)	
Package Type	Foil pouch
Package Quantity	16 ounces
Tobacco Cut Size	(b) (4) CPI[1]
Characterizing Flavor	Blackberry[2]
Attributes of SE Report	
Applicant	Swedish Match USA, Inc.
Report Type	Regular Product Quantity Change
Product Category	Smokeless Tobacco Products
Product Sub-Category	Loose Chewing Tobacco
Recommendation	
Issue Substantially Equivalent (SE) order.	

[1] Cuts per inch

[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.

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2020.01.08 14:13:11 -05'00'

Colleen K. Rogers, Ph.D.
Director
Division of Product 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: 2020.01.08 15:39:36 -05'00'

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

TABLE OF CONTENTS

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0015538: Big Duke Sweet Blend (16 oz.)	
Product Name	Southern Pride Blackberry Blend
Package Type	Foil pouch
Package Quantity	3 ounces
Tobacco Cut Size	(b) (4) CPI[1]
Characterizing Flavor	Blackberry[2]

The predicate tobacco product is a loose chewing tobacco, smokeless tobacco product manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On October 18, 2019, FDA received a SE Report from Swedish Match USA, Inc. FDA issued an Acceptance letter to the applicant on October 23, 2019. On October 29, 2019, FDA requested information on the grandfathered tobacco product. The applicant submitted a response to the Information Request on October 31, 2019 (SE0015550).

Product Name	SE Report	Amendment
Big Duke Sweet Blend (16 oz.)	SE0015538	SE0015550

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for this SE Report.

2. REGULATORY REVIEW

A regulatory review was completed by Shireen Fotelargias on October 23, 2019.

The review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the predicate tobacco product is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated November 17, 2019, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and, therefore, an eligible predicate tobacco product.

OCE also completed a review to determine whether the new tobacco product is 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 January 8, 2020, concludes that the new tobacco product is in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

A scientific review was completed by the Office of Science (OS) for the following discipline:

4.1. SOCIAL SCIENCE

A social science review was completed by Katherine Margolis on December 6, 2019.[3]

The social science review concludes that the new tobacco product has different characteristics from the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health from a social science perspective. The review identified the following difference between the new and predicate tobacco product:

- 433% increase in product quantity (3 ounces to 16 ounces)

The review concludes that there is no available scientific evidence on the influence that loose chewing tobacco package quantity has on consumer perceptions of harm or use intentions to indicate that an increase of this magnitude would cause the new tobacco product to raise different questions of public health from a social science perspective. Therefore, the review concludes that the differences between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from a social science perspective.

Moreover, the Office of Science (OS) prepared a memorandum[4] summarizing its current thinking on product quantity changes, which further supports OS' determination that, at this time, changes in tobacco product quantity do not cause new tobacco products to raise different questions of public health. Consequently, the change in product quantity does not cause the new tobacco product to raise different questions of public health from a social science perspective.

The social science review also evaluated the applicant's rationale for the apparent change in characterizing flavor. The applicant originally listed the characterizing flavor of the new and predicate tobacco products as "none"; however, the characterizing flavor of the grandfathered tobacco product (i.e., the predicate tobacco product) is "blackberry." In amendment SE0015550, the applicant explains that the grandfathered product on record has a characterizing flavor of "blackberry" principally because "blackberry" was contained in the product's name. The applicant further states that the flavor can best be categorized as a (b) (4) or a (b) (4) but it may not be considered a distinct flavor or a discrete "blackberry" flavor by a consumer. Thus, the applicant indicated "none" as the characterizing flavor. The applicant also stated, "Furthermore, we would like to amend the characterizing flavor of the new product from

[3] The social science review incorrectly identifies this as a full SE Report rather than a product quantity change SE Report.
[4] *See* memorandum on product quantity changes, dated December 7, 2017.

"none" to "blackberry" in our application so that it is clear there has been no change in characterizing flavor and to remain consistent with prior information submitted to FDA." Since the applicant indicates that there is no change in characterizing flavor between the new and predicate tobacco products, this does not cause the new tobacco product to raise different questions of public health from a social science perspective.

The review also evaluated the health information summary for the SE Report. FDA has determined that the health information summary provided for this SE Report would not cause a violation of section 911 of the FD&C Act upon introduction or delivery for introduction of the new tobacco product into interstate commerce.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Dilip Venugopal on December 6, 2019.

The environmental review found that the applicant did not provide the first- and fifth-year projected market volumes of the predicate tobacco product, which is used to quantitatively assess the environmental impact of concurrent manufacturing, use, and disposal of the new and predicate tobacco products. 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 tobacco product characteristics of the new and predicate tobacco products are identical except for a change in product quantity from 3 ounces to 16 ounces (433% increase).

The social science review and the finalized memorandum[4] conclude that based on OS's experience and the currently available evidence, the increase in product quantity does not cause the new tobacco product to raise different questions of public health. I concur with this conclusion.

The predicate tobacco product in SE0015538 meets statutory requirements because it was determined that it is a grandfathered tobacco product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

The new tobacco product is currently in compliance with the FD&C Act.

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

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

1. Your SE Report indicates that the predicate tobacco product will continue to be manufactured and marketed after receiving a marketing order for the new tobacco product. The projected market volumes for the new tobacco product are included in your SE Report. For the predicate tobacco product, provide the current market volume and the projected

market volumes in the first year and the fifth year of marketing the new tobacco product. A table is included for this information; however, you can submit this information with an alternative approach if it provides the first- and fifth-year market volume projections for the predicate tobacco product. Marketing information is used to quantitatively assess the environmental impact of concurrent manufacturing, use, and disposal of the new and predicate tobacco products.

Table 1. Predicate Tobacco Product Market Volumes				
Predicate Tobacco Product	**Unit**	**Current Market Volume**	**First-Year Market Volume**	**Fifth-Year Market Volume**
Southern Pride Blackberry Blend				

If the applicant adequately responds to the request and an EIS or FONSI is completed, an SE order letter should be issued for the new tobacco product in SE0015538, as identified on the cover page of this review.