FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0015376

SE0015376: Natural American Spirit Perique Blend Pouch	
Package Type	Pouch
Package Quantity	40 grams
Characterizing Flavor	None
Attributes of SE Report	
Applicant	Santa Fe Natural Tobacco Company Inc.
Report Type	Regular
Product Category	Roll-Your-Own
Product Sub-Category	Roll-Your-Own Tobacco Filler
Recommendation	
Issue a Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Gloria J. Kulesa -S
Date: 2019.10.17 09:06:18 -04'00'

Gloria Kulesa
Engineering Branch Chief
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: 2019.10.17 09:48:33 -04'00'

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:

SE0015376: Natural American Spirit Perique Blend Pouch	
Product Name	Natural American Spirit Perique Blend Pouch
Package Type	Pouch
Package Quantity	40 g
Characterizing Flavor	None

The predicate tobacco product is a roll-your-own tobacco filler manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On July 30, 2019, FDA received one SE Report from Santa Fe Natural Tobacco Company Inc. FDA issued an Acknowledgement letter to the applicant on August 2, 2019.

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 Camille Hayslett on August 2, 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 August 26, 2019, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and, therefore, is 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 October 8, 2019 concludes that the new tobacco product is in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

Scientific reviews were completed by the Office of Science (OS) for the following disciplines:

4.1. CHEMISTRY

A chemistry review was completed by Abdur-Rafay Shareef on September 18, 2019.

The chemistry review concludes that the new tobacco product has different characteristics related to product chemistry compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- (b) (4) in perique, 2% decrease in [redacted], and 0.3% increase in total tobacco in the new tobacco product compared to the predicate tobacco product,
- 5% increase in NNN, 3% decrease in nicotine, and a 20% decrease in NNK levels in the new tobacco product compared to the predicate tobacco product.

Beside the changes in the tobacco blend, the new and predicate tobacco products do not contain any ingredients other than tobacco. In support of these tobacco blend changes, the applicant submitted filler levels for NNN, NNK, and total nicotine. Chemistry finds the decrease in NNK level of 20% between the new and predicate tobacco products to be analytically inequivalent. Therefore, chemistry defers the NNK level to toxicology for further consideration. For NNN and total nicotine, chemistry determines that the new and predicate tobacco products are analytically equivalent and no further information is necessary. Therefore, the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health from a chemistry perspective.

4.2. ENGINEERING

An engineering review was completed by Michael Morschauser on September 13, 2019.

The engineering review did not identify any differences in characteristics between the new and predicate tobacco product that could cause the new tobacco product to raise different questions of public health from an engineering perspective. Therefore, the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health related to product engineering.

4.3. MICROBIOLOGY

A microbiology review was completed by Prashanthi Mulinti on September 18, 2019.

The microbiology review concludes that the new tobacco product has different characteristics related to product microbiology compared to the predicate tobacco product, but the difference does not cause the new tobacco product to raise different questions of public health. The review identifies the following difference:

- (b) (4) in perique tobacco

The tobacco blend of the new and predicate tobacco products includes identical tobacco types but differs in the relative amounts of the tobacco types in the blend, resulting in a 2% decrease and a(b) (4) in target amounts of [redacted] and perique tobacco, respectively, in the new tobacco product. Perique tobacco is fermented, and microbial-mediated reactions during fermentation play a key role in the accumulation of TSNAs in the fermented tobacco products. Therefore, the(b) (4) in perique tobacco in the new tobacco product could potentially affect the stability of the new tobacco product. However, this (b) (4) is not of concern from microbiology because perique tobacco contributes to only 10% and 8% of the overall tobacco blend of the new and predicate tobacco products, respectively. Additionally, the total moisture content of the new and predicate tobacco products is approximately 15%, which is insufficient to support fungal growth. Scientific evidence supporting bacterial growth in tobacco at moisture contents of approximately 15% is not currently available. Based on the contribution of the perique tobacco to the overall tobacco blend of the finished new and predicate tobacco products, moisture content, and analytically equivalent NNN levels in the new and predicate tobacco products, the(b) (4) in perique tobacco in the new tobacco product, compared to the predicate tobacco product, does not cause the new tobacco product to raise different questions of public health from a microbiological perspective. Although the microbiology reviewer stated that NNK was analytically equivalent, this statement is inaccurate. The (b) (4) in perique tobacco did not contribute to an increase in the NNK level. In fact, the NNK level decreased in the new tobacco product which was further evaluated by the toxicology reviewer. This does not alter the conclusion of the microbiology review. Therefore, the difference in characteristics between the new and predicate tobacco products does not cause the new tobacco product to raise different questions of public health from a microbiology perspective.

4.4. TOXICOLOGY

A toxicology review was completed by Juan Crespo-Barreto on September 20, 2019.

The toxicology review concludes that the new tobacco product has different characteristics related to product toxicology compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- (b) (4) in the perique and a 2% decrease in the [redacted] tobacco levels in the new tobacco product compared to the predicate tobacco product.

The changes in tobacco blend composition did not produce analytically important changes in the NNN level in the unburned tobacco filler of the new tobacco product compared to the predicate tobacco product. Although not explicitly stated by toxicology, NNK levels decreased 20% in the new tobacco product in comparison to the predicate tobacco product. Therefore, the NNK level does not cause the new tobacco product to raise different questions of public health. Therefore, the difference in characteristics between the new and predicate tobacco product does not cause the new tobacco product to raise different questions of public health

from a toxicology perspective. Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from a toxicology perspective.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Shannon Hanna on September 12, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on September 12, 2019. The FONSI was supported by an environmental assessment prepared by FDA on September 12, 2019.

6. CONCLUSION AND RECOMMENDATION

The following are the key differences in characteristics between the new and predicate tobacco products:

- (b) (4) in perique, 2% decrease in [redacted], and 0.3% increase in total tobacco in the new tobacco product compared to the predicate tobacco product,
- 5% increase in NNN, 3% decrease in nicotine, and a 20% decrease in NNK levels in the new tobacco product compared to the predicate tobacco product.

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health.

The tobacco product design specifications for the new and predicate tobacco product are identical and no other ingredients, beside tobacco, are found in the new and predicate tobacco products. Therefore, these do not cause the new tobacco product to raise different questions of public health. The applicant indicated changes were made to the tobacco blend. Changes to the tobacco blend may result in differences in HPHC delivery of the new tobacco product when compared to the predicate tobacco product. A discussion of the specific changes in the tobacco blend is addressed in the chemistry and toxicology summaries in section 4, above. In support of the tobacco blend changes, the applicant provided measured HPHC levels for NNN, NNK, and total nicotine of the new and predicate tobacco products. Based on the chemistry review, the changes in the tobacco blend composition demonstrated that the measured HPHCs levels for total nicotine and NNN in the new tobacco product are analytically equivalent to the predicate tobacco product. Therefore, these levels do not cause the new tobacco product to raise different questions of public health. For NNK, chemistry determined that the 20% decrease in the yield in the new tobacco product was not analytically equivalent. However, this is a decrease in the NNK level measured in the new product, and therefore, it does not cause the new tobacco product to raise different questions of public health. The new tobacco product has a (b) (4) in perique tobacco. Perique tobacco is fermented and microbial-mediated reactions during the fermentation process may affect TSNA levels in fermented tobacco products. However, the (b) (4) is not of concern from microbiology because perique tobacco contributes to only a very small percentage of the total tobacco blend. Additionally, the difference in the NNN levels between the new and predicate tobacco products were analytically equivalent. Finally, the total moisture content is insufficient to support fungal

growth. Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health.

The predicate tobacco product 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. In addition, all of the scientific reviews conclude that the differences between the new and predicate tobacco product are such that the new tobacco product does not raise different questions of public health. I concur with these reviews and recommend that an SE order letter be issued.

FDA examined the environmental effects of finding this new tobacco product substantially equivalent and made a finding of no significant impact.

An SE order letter should be issued for the new tobacco product in SE0015376, as identified on the cover page of this review.