FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0015123 - SE0015125

SE0015123: Husky Long Cut Wintergreen	
Package Type	Plastic Can and Plastic Lid
Package Quantity	34.02 grams
Tobacco Cut Size	[redacted] Cuts per Inch (CPI)
Characterizing Flavor	Wintergreen
SE0015124: Skoal Bandits Mint	
Package Type	Plastic Can with Metal Lid
Package Quantity	14.10 grams
Portion Count	20 Portions
Portion Mass	705 mg/portion
Portion Length	35 mm
Portion Width	16 mm
Portion Thickness	3.52 mm[1]
Tobacco Cut Size	[redacted] CPI
Characterizing Flavor	Mint
Additional Property	Fine Cut
SE0015125: Skoal Pouches Apple Tobacco Blend	
Package Type	Plastic Can with Metal Lid
Package Quantity	23.25 grams
Portion Count	15 Portions
Portion Mass	1550 mg/portion
Portion Length	40 mm
Portion Width	18 mm
Portion Thickness	5.96 mm[1]
Tobacco Cut Size	[redacted] CPI
Characterizing Flavor	Apple
Additional Property	Fine Cut
Attributes of SE Reports	
Applicant	U.S. Smokeless Tobacco Company LLC
Report Type	Regular
Product Category	Smokeless Tobacco Products
Product Sub-Category	Loose (SE0015123) and portioned moist snuff (SE0015124 and SE0015125)
Recommendation	
Issue Substantially Equivalent (SE) orders.	

[1] Calculated value

Technical Project Lead (TPL):

Digitally signed by Shixia Feng -S
Date: 2019.06.17 08:59:10 -04'00'

Shixia Feng, Ph.D.
Chemistry 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: 2019.06.17 13:42:46 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0015123: Husky Long Cut Wintergreen	
Product Name	Husky Long Cut Wintergreen
Package Type	Plastic Can and Plastic Lid
Package Quantity	34.02 grams
Tobacco Cut Size	[redacted] CPI
Characterizing Flavor	Wintergreen
SE0015124: Skoal Bandits Mint	
Product Name	Skoal Bandits Mint
Package Type	Plastic Can with Metal Lid
Package Quantity	14.10 grams
Portion Count	20 Portions
Portion Mass	705 mg/portion
Portion Length	35 mm
Portion Width	16 mm
Portion Thickness	3.52 mm[1]
Tobacco Cut Size	[redacted] CPI
Characterizing Flavor	Mint
Additional Property	Fine Cut
SE0015125: Skoal Pouches Apple Tobacco Blend	
Product Name	Skoal Pouches Apple Blend
Package Type	Plastic Can with Metal Lid
Package Quantity	23.25 grams
Portion Count	15 Portions
Portion Mass	1550 mg/portion
Portion Length	40 mm
Portion Width	18 mm
Portion Thickness	5.96 mm[1]
Tobacco Cut Size	[redacted] CPI
Characterizing Flavor	Apple
Additional Property	Fine Cut

The predicate tobacco products are loose (SE0015123) and portioned moist snuff (SE0015124 and SE0015125) smokeless tobacco products manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 19, 2019, FDA received three SE Reports from Altria Client Services LLC (ALCS) on behalf of U.S. Smokeless Tobacco Company LLC (USSTC). FDA issued Acknowledgement letters to the applicant on March 27, 2019.

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

A regulatory review was completed by Samuel Motto on March 27, 2019.

The review concludes that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (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 April 17, 2019 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), as required by section 905(j)(1)(A)(i) of the FD&C Act. The OCE review[2] dated May 24, 2019 concludes that the new tobacco products are 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 Mimy Young on April 25, 2019.

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

[2] An addendum review was completed on June 12, 2019, to correctly identify SE0015124-SE0015125 as portioned moist snuff.

- Addition of (b) (4) (b) (4) mg/g in SE0015123; (b) (4) mg/pouch in SE0015124; and (b) (4) mg/pouch in SE0015125)
- Replacement of (b) (4) with same quantities of [redacted] (b) (4) -8 mg/g in SE0015123; (b) (4) -8 mg/pouch in SE0015124; and (b) (4) -8 mg/pouch in SE0015125)
- Addition of [redacted] (b) (4) mg/g in SE0015123; (b) (4) mg/pouch in SE0015124; and (b) (4) mg/pouch in SE0015125)

The applicant provided a certification statement from a responsible official authorized to act on behalf of U.S. Smokeless Tobacco Company LLC stating that the characteristics (e.g., materials, ingredients, design features, heating source, or any other feature) are "identical" with minor differences in the (b) (4) component. All SE Reports contain (b) (4) (b) (4) that is not present in the corresponding predicate products. Because the differences in the (b) (4) [redacted] blend quantities between the new and predicate products contribute to minor differences in the finished product weight, the new tobacco products do not raise different questions of public health from a chemistry perspective.

Moreover, all SE Reports replace (b) (4) [redacted] in the predicate products with the same quantities of (b) (4) in the new tobacco products. In addition, all SE Reports contain (b) (4) that is not present in the corresponding predicate products. Because the quantities of ingredients in the (b) (4) contribute to < 0.1% of the finished product weight, the differences in (b) (4) [redacted] do not cause the new tobacco products to raise different questions of public health from a chemistry perspective. Further evaluations of these differences are deferred to toxicology and microbiology reviews.

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

4.2. MICROBIOLOGY

A microbiology review was completed by Prashanthi Mulinti on April 30, 2019.

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

- Addition (b) (4) mg/g) of (b) (4) [redacted] to replace identical amount of non-(b) (4) [redacted]
- Addition (b) (4) mg/g) of (b) (4) [redacted]
- Addition (b) (4) mg/g) of a preservative, (b) (4) [redacted]

For each SE report, the applicant provided a certification statement indicating that the new and corresponding predicate tobacco products differ only in the composition of the (b) (4) The

(b) (4) component of the new tobacco products includes addition of (b) (4) (preservative) and (b) (4) to replace the (b) (4) that is added to the (b) (4) component of the corresponding predicate tobacco products. The applicant provided data to show that the (b) (4) component added to the new tobacco products contributes only a small amount of (b) (4) ((b) (4) mg/g), (b) (4) (b) (4) mg/g) and (b) (4) ((b) (4) mg/g) to the finished new tobacco products when compared to the corresponding predicate tobacco products. From a microbiology perspective, the small amounts of (b) (4) and (b) (4) added to the finished new tobacco products in this review are not of concern. However, the addition of a preservative could potentially affect the microbial stability of the new tobacco products. The amount of (b) (4) added to the new tobacco products is small ((b) (4) mg/g) and conventional microbial assays are not sensitive enough to assess such small difference in the concentration of an analyte between the tobacco products. Therefore, from a microbiology perspective, the small amount ((b) (4) mg/g) of (b) (4) added to the new tobacco products in this review does not cause the new tobacco products to raise different questions of public health. Based on this information provided for the new and corresponding predicate tobacco product in this review and the certification statement, the differences in composition of the (b) (4) component of the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a microbiology perspective.

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

4.3. TOXICOLOGY

A toxicology review[3] was completed by Juan Crespo-Barreto on May 8, 2019.

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

- Addition of (b) (4)
- Replacement of complex ingredient (b) (4) (b) (4)
- Addition of (b) (4)

The magnitude of changes in tobacco blend and other ingredients (b) (4) is less than 0.1%. At the indicated levels, changes are not expected to increase the levels of harmful and potential harmful constituents (HPHCs). The (b) (4) formulation in the new products only contains chemicals with low risk of oral toxicity at the specified quantities, thus the toxicity of the new products is expected to be no worse than the corresponding

[3] An addendum review was completed on June 13, 2019, to correctly identify the predicate Tobacco product for SE0015125 as Skoal Pouches Apple Blend.

predicate products. Based on the estimated daily exposure for average consumers, oral (b) (4) exposure associated with the new products is below relevant toxicity-based reference values of (b) (4) intake established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and EPA. Therefore, from a toxicological perspective, available scientific data support that the addition or increase of these tobacco blend components and ingredients, at the provided levels, are unlikely to cause the new products to raise different questions of public health.

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

5. ENVIRONMENTAL DECISION

An environmental review[4] was completed by Thomas Creaven on April 12, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on May 17, 2019. The FONSI was supported by an environmental assessment prepared by FDA on May 17, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Addition of (b) (4) (b) (4) mg/g in SE0015123; (b) (4) mg/pouch in SE0015124; and (b) (4) mg/pouch in SE0015125)
- Replacement of (b) (4) with same quantities of (b) (4) (b) (4) mg/g in SE0015123; (b) (4) mg/pouch in SE0015124; and (b) (4) mg/pouch in SE0015125)
- Addition of (b) (4) (b) (4) mg/g in SE0015123; (b) (4) mg/pouch in SE0015124; and (b) (4) mg/pouch in SE0015125)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The changes are only made to the (b) (4) portion of the products. At the indicated levels, changes are not expected to increase the levels of HPHCs. The toxicology review concluded that the (b) (4) formulation in the new tobacco products only contains chemicals with low risk of oral toxicity at the specified quantities, thus the toxicity of the new products is expected to be no worse than the corresponding predicate tobacco products. Based on the estimated daily exposure for average consumers, oral (b) (4) exposure associated with the new tobacco products is below relevant toxicity-based reference values of (b) (4) intake established by the JECFA and EPA. Furthermore, microbiology review concluded that the changes are too small to have measurable effects by the conventional microbial assays. Therefore, the differences in characteristics between the new and

[4] An addendum review was completed on June 11, 2019, to correctly identify the predicate Tobacco product for SE0015124 - SE0015125 as portioned moist snuff.

corresponding predicate products do not cause the new tobacco products to raise different questions of public health.

The predicate tobacco products meet statutory requirements because it was determined that they are grandfathered tobacco 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. In addition, all of the scientific reviews conclude that the differences between the new and corresponding predicate tobacco products are such that the new tobacco products do not raise different questions of public health. I concur with these reviews and recommend that SE order letters be issued.

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

SE order letters should be issued for the new tobacco products in SE0015123 - SE0015125, as identified on the cover page of this review.