FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review:

SE0015011 and SE0015019

SE0015011: Skoal Long Cut Apple Tobacco Blend	
Package Type	Plastic Can and Metal Lid
Package Quantity	34.02 grams (g)
Tobacco Cut Size	(b) (4)
Characterizing Flavor	Apple
SE0015019: Skoal Long Cut Peach Tobacco Blend	
Package Type	Plastic Can and Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b) (4)
Characterizing Flavor	Peach
Common Attributes of SE Reports	
Applicant	U.S. Smokeless Tobacco Company LLC
Report Type	Regular
Product Category	Smokeless Tobacco Product
Product Sub-Category	Loose Moist Snuff
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Kenneth Taylor -S
Date: 2019.03.05 12:22:30 -05'00'

Kenneth M. Taylor, 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: 2019.03.05 14:22:06 -05'00'

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0015011: Skoal Long Cut Apple Tobacco Blend	
Product Name	Skoal Long Cut Apple Blend
Package Type	Plastic Can and Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b) (4)
Characterizing Flavor	Apple
SE0015019: Skoal Long Cut Peach Tobacco Blend	
Product Name	Skoal Long Cut Peach Blend
Package Type	Plastic Can and Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b) (4)
Characterizing Flavor	Peach

The predicate tobacco products are loose moist snuff smokeless tobacco products manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On December 6, 2018, FDA received two SE Reports from Altria Client Services LLC (ALCS) on behalf of U.S. Smokeless Tobacco Company LLC (USSTC). FDA issued an Acknowledgement letter to the applicant on December 13, 2018. No amendments were submitted.

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

Regulatory reviews were completed by Pin Zhang on December 13, 2018.

The final reviews conclude 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 in SE0015011 and SE0015019 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 December 26, 2018,

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 January 31, 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

The chemistry review was completed by Selvin Edwards on January 27, 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:

- Replacement of non-GRAS (b) (4) (b) (4) with nearly an identical amount of (b) (4) (GRAS)
- Addition of (b) (4) tobacco
- Addition of (b) (4)

All of the ingredient changes occur in the (b) (4) tobacco, which comprises (b) (4) of the finished tobacco product. The amounts of (b) (4) and (b) (4) in the finished product is approximately (b) (4) respectively. These ingredient changes are in amounts that are minor, relative to the amount of the finished tobacco products, and do not cause concerns.

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. ENGINEERING

The engineering review was completed by Drew Katherine on January 25, 2019.

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

4.3. MICROBIOLOGY

A microbiology review was completed by Wen Lin on January 24, 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) tobacco
- Addition (b) (4)
- Replacement of non-GRAS (b) (4) with (b) (4) GRAS (b) (4)

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) process. The (b) (4) tobacco component of the new tobacco products includes the addition of (b) (4) (b) (4) (b) (4) as a (b) (4) and (b) (4) replaces the (b) (4) (b) (4) The (b) (4) tobacco component (b) (4) to the new tobacco products contributes only a small amount of (b) (4) (b) (4) (b) (4) (b) (4) and (b) (4) (b) (4) to the final new tobacco products when compared to the corresponding predicate tobacco products. These are relatively small ingredient differences in composition of the (b) (4) tobacco component compared to the corresponding predicate tobacco products.

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 related to product microbiology.

4.4. TOXICOLOGY

A toxicology review was completed by Maocheng Yang on January 23, 2019.

The toxicology review concludes that the new tobacco products have different characteristics related to product 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) tobacco stem
- Substitution of (b) (4)
- Addition of (b) (4)

The (b) (4) tobacco replaces a similar amount of (b) (4) tobacco and would have a potentially favorable effect in decreasing NNK and NNN levels. However, because the amount is so small, any effect on these HPHCs cannot be measured. Due to the relatively minor amount and tobacco type, this tobacco blend change is not anticipated to cause toxicological concerns. (b) (4) contains significantly fewer ingredients than (b) (4)

(b) (4) and some of those removed ingredients are of toxicological concern. Because the amount of the substituted ingredient is sub-nanogram in quantity and has fewer ingredients, the substitution is not a concern. The addition of (b) (4) is estimated to result in a daily exposure level of (b) (4) adult consumers who use one can of the new products per day. This is significantly less than the US EPA's risk assessment for inorganic chlorate exposure, which has a calculated chronic population adjusted dose (cPAD) of 0.03 mg/kg/day. Accordingly, the addition of (b) (4) to the new tobacco products at the indicated levels is not anticipated to raise toxicological concerns.

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

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on March 5, 2019. The FONSI was supported by an environmental assessment prepared by FDA on March 5, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Addition (b) (4)
- Addition (b) (4)
- Replacement of non-GRAS (b) (4) with (b) (4) GRAS (b) (4) oil

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. There are no product design differences between the new and corresponding predicate tobacco products. The only differences in characteristics are ingredient changes to the (b) (4) tobacco component in very minor amounts. These ingredient changes won't cause measurable effects on harmful and potentially harmful constituents like NNK and NNN or other toxicants; or are 10^{-6} – fold less than calculated risk exposure amounts. Therefore, the differences in characteristics between the new and 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 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 SE0015011 and SE0015019, as identified on the cover page of this review.