U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0015017, SE0015020 and SE0015022

SE0015017: Skoal Pouches Mint	
Package Type	Plastic Can and Metal Lid
Package Quantity	23.25 g
Portion Count	15 portions
Portion Mass	1550 mg
Portion Length	40 mm
Portion Width	18 mm
Portion Thickness	6.01 mm
Tobacco Cut Size	(b Cuts per Inch {CPI}
Characterizing Flavor	Mint
Additional Property	Fine cut
SE0015020: Skoal Pouches Wintergreen	
Package Type	Plastic Can and Metal Lid
Package Quantity	23.25 g
Portion Count	15 portions
Portion Mass	1550 mg
Portion Length	40 mm
Portion Width	18 mm
Portion Thickness	6.07 mm
Tobacco Cut Size	(b CPI
Characterizing Flavor	Wintergreen
Additional Property	Fine cut
SE0015022: Skoal Pouches Berry Tobacco Blend	
Package Type	Plastic Can and Metal Lid
Package Quantity	23.25 g
Portion Count	15 portions
Portion Mass	1550 mg
Portion Length	40 mm
Portion Width	18 mm
Portion Thickness	6.19 mm
Tobacco Cut Size	(b CPI
Characterizing Flavor	Berry
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	Portioned, moist snuff
Recommendation	
Issue Substantially Equivalent {SE} orders.	

Technical Project Lead (TPL):

Melissa Mcculloch -S
Digitally signed by Melissa Mcculloch -S
Date: 2019.03.04 10:28:13 -05'00'

Melissa McCulloch, Ph.D.
Senior Regulatory Scientist
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 Glen D. Jones -S
Date: 2019.03.04 15:13:15 -05'00'

For 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:

SE0015017: Skoal Pouches Mint	
Product Name	Skoal Pouches Mint
Package Type	Plastic Can and Metal Lid
Package Quantity	23.25 g
Portion Count	15 portions
Portion Mass	1550 mg
Portion Length	40 mm
Portion Width	18 mm
Portion Thickness	6.01 mm
Tobacco Cut Size	(b CPI
Characterizing Flavor	Mint
Additional Property	Fine cut
SE0015020: Skoal Pouches Wintergreen	
Product Name	Skoal Pouches Wintergreen
Package Type	Plastic Can and Metal Lid
Package Quantity	23.25 g
Portion Count	15 portions
Portion Mass	1550 mg
Portion Length	40 mm
Portion Width	18 mm
Portion Thickness	6.07 mm
Tobacco Cut Size	(b CPI
Characterizing Flavor	Wintergreen
Additional Property	Fine cut

SE0015022: Skoal Pouches Berry Tobacco Blend	
Product Name	Skoal Pouches Berry
Package Type	Plastic Can and Metal Lid
Package Quantity	23.25 g
Portion Count	15 portions
Portion Mass	1550 mg
Portion Length	40 mm
Portion Width	18 mm
Portion Thickness	6.19 mm
Tobacco Cut Size	(b CPI
Characterizing Flavor	Berry
Additional Property	Fine cut

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On December 6, 2018, FDA received three SE Reports from Altria Client Services LLC on behalf of U.S. Smokeless Tobacco Company LLC. 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

A regulatory review was completed by Maria Suarez on December 13, 2018.

The review conclude that the SE Reports are 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 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 review dated January 3, 2019, concludes 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 dated February 11, 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 Youbang Liu on January 24, 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 ingredient differences in the fermented tobacco component:

- Addition of (b) (4) mg/g {finished product} (b) (4)
- Addition of (b) (4) mg/g {finished product} (b) (4)
- (b) (4) mg/g {finished product} (b) (4) is replaced with the same amount of (b) (4)

The new and corresponding predicate tobacco products have differences in the composition of (b) (4) {0.09% of total tobacco product weight}. The differences include the addition of (b) (4) mg/g (b) (4) and (b) (4) mg/g (b) (4) in the new tobacco products and replacing (b) (4) mg/g (b) (4) in the predicate tobacco products with (b) (4) in the corresponding new tobacco products. These minor differences between the new and corresponding predicate tobacco products are not expected to impact HPHC amounts. 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 David Craft on January 31, 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 ingredient differences in the fermented tobacco component:

- Addition of (b) (4) mg/g {finished product} (b) (4)
- Addition of (b) (4) mg/g {finished product} (b) (4)
- (b) (4) mg/g {finished product} (b) (4) is replaced with the same amount of (b) (4)

The applicant provided a certification statement indicating that the new and corresponding predicate tobacco products differ only in the composition of the fermented tobacco component that is used as (b) to initiate the fermentation process. As discussed in Section 4.1, Chemistry, the differences in composition of the fermented tobacco component between the new and corresponding predicate tobacco products are minor. These minor differences are not expected to impact the microbial stability of the new and corresponding 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 from a microbiology perspective.

4.3. TOXICOLOGY

A toxicology review was completed by Yanling Chen on January 31, 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 ingredient differences in the fermented tobacco component:

- Addition of (b) (4) mg/g {finished product} (b) (4)
- Addition of (b) (4) mg/g {finished product} (b) (4)
- (b) (4) mg/g {finished product} (b) (4) is replaced with the same amount of (b) (4)

As discussed in Section 4.1, Chemistry, the differences in composition of the fermented tobacco component between the new and corresponding predicate tobacco products are minor. Available scientific data supports that these minor differences are not expected to impact the toxicology of the new and corresponding predicate 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 from a toxicology perspective.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Rudaina Alrefai-Kirkpatrick on January 15, 2019.

A finding of no significant impact {FONSI} was signed by Hans Rosenfeldt, Ph.D. for Kimberly Benson, Ph.D. on February 28, 2019. The FONSI was supported by an environmental assessment prepared by FDA on February 28, 2019.

6. CONCLUSION AND RECOMMENDATION

The new and corresponding predicate tobacco products have ingredient differences in the fermented tobacco component {0.09% of total tobacco product weight}. The differences include:

- Addition of (b) (4) mg/g {finished product} (b) (4)
- Addition of (b) (4) mg/g {finished product} (b) (4)
- (b) (4) mg/g {finished product} (b) (4) is replaced with the same amount of (b) (4)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The amount of the ingredient differences in the fermented tobacco component are minor and not expected to impact the HPHC amounts, microbial stability or toxicology of the new and corresponding predicate 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.

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 SE0015017, SE0015020 and SE0015022, as identified on the cover page of this review.