FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review:

SE0014607 - SE0014611

SE0014607: Skoal Long Cut Classic	
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b)(4)
Characterizing Flavor	None
SE0014608: Skoal Long Cut Classic Wintergreen	
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b)(4)
Characterizing Flavor	Wintergreen
SE0014609: Skoal Long Cut Classic Mint	
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b)(4)
Characterizing Flavor	Mint
SE0014610: Skoal Long Cut Classic Straight	
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b)(4)
Characterizing Flavor	None
SE0014611: Skoal Long Cut Spearmint	
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b)(4)
Characterizing Flavor	Spearmint
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: 2018.06.27 11:35:41 -04'00'

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 Glen D. Jones -S
Date: 2018.06.28 14:14:34 -04'00'

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:

SE0014607: Skoal Long Cut Classic	
Product Name	Skoal Long Cut Classic
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b)(4)
Characterizing Flavor	None
SE0014608: Skoal Long Cut Classic Wintergreen	
Product Name	Skoal Long Cut Wintergreen
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b)(4)
Characterizing Flavor	Wintergreen
SE0014609: Skoal Long Cut Classic Mint	
Product Name	Skoal Long Cut Mint
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b)(4)
Characterizing Flavor	Mint
SE0014610: Skoal Long Cut Classic Straight	
Product Name	Skoal Long Cut Straight
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b)(4)
Characterizing Flavor	None
SE0014611: Skoal Long Cut Spearmint	
Product Name	Skoal Long Cut Spearmint
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b)(4)
Characterizing Flavor	Spearmint

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received five SE Reports (SE0014607, SE0014608, SE0014609, SE0014610, and SE0014611) on April 5, 2018, from Altria Client Services, Inc. on behalf of U.S. Smokeless Tobacco Company. FDA Issued Acknowledgement letters on April 12, 2018.

Product Name	SE Report	Amendments
Skoal Long Cut Classic	SE0014607	None
Skoal Long Cut Classic Wintergreen	SE0014608	
Skoal Long Cut Classic Mint	SE0014609	
Skoal Long Cut Classic Straight	SE0014610	
Skoal Long Cut Spearmint	SE0014611	

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 Antonio Thornton on April 12, 2018.

The 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 are grandfathered products (i.e., were commercially marketed other than exclusively in test markets as of February 15, 2007). The OCE reviews dated May 11, 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 May 30, 2018, 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 Jiu Ai on May 22, 2018.

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 difference:

- Replacement of non-GRAS[1] rose type absolute with GRAS (b)(4)

The new tobacco products have the same characteristics as the corresponding predicate tobacco products except that 0.1 µg/g of the GRAS (b)(4) replaces an equal amount of non-GRAS (b)(4) 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 Michael Morschauser on May 22, 2018.

The engineering review did not identify any differences in characteristics between the new and corresponding predicate tobacco products from an engineering perspective. Therefore, from an engineering perspective, the new and corresponding predicate tobacco products have the same characteristics.

4.3. MICROBIOLOGY

The microbiology review was completed by Wen Lin on May 24, 2018.

The microbiology 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 a microbiology perspective. Therefore, from a microbiology perspective, the new and corresponding predicate tobacco products have the same characteristics.

4.4. TOXICOLOGY

The toxicology review was completed by Juan Crespo-Barreto on May 29, 2018.

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 difference:

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

(b)(4) (GRAS) contains 32 fewer ingredients than (b)(4) . (b)(4) (GRAS) also has one new ingredient and six other ingredients that are increased in comparison

[1] GRAS: Generally Recognized as Safe and Effective

to (b)(4) (non-GRAS (b)(4)). However, the amounts of the added and increased ingredients are less than published reference values for safe oral exposures. 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 Catherine McCollum on May 25, 2018.

The environmental review found that the SE Reports do not provide enough information for an Environmental Assessment for the new products as required in 21 CFR 25.40. Specifically, the environmental review found:

- The applicant was unclear about the marketing intention of the predicate products if they receive marketing orders for the new products.
- The applicant did not provide the current market volumes for the predicate products.
- The packaging information for the new products is inadequate to complete the EAs. The applicant did not specify whether each unit would be encased in a plastic overwrap, whether the units would be packaged in a sleeve or a retail box, the number of units per retail box or shipping case, and the composition of such packaging materials.

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

- Replacement of (b)(4) (non-GRAS) with equal quantity of (b)(4) (GRAS)

The applicant has demonstrated that this different characteristic does not cause the new tobacco products to raise different questions of public health. This is a single ingredient change that is present in the new tobacco products at an extremely small amount. Furthermore, the quantities of ingredients comprising (b)(4) (GRAS) are less than established safe limits oral exposures. Therefore, the difference in characteristics between the new and corresponding predicate products does 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 found additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing an SE order.

An Advice/Information Request letter should be issued requesting the following information:

1. All of your SE Reports are unclear regarding the marketing intention of the predicate products. Marketing information is used to quantitatively assess the environmental impact of manufacturing, use and disposal of the new products as compared to the predicate products. You note that the new products will replace the predicate products; however, you don't directly state that marketing of the predicate products will be discontinued. Provide the following information:

    a. Specify whether or not the predicate products will be simultaneously marketed with the new products.

    b. If the predicate products are to be marketed simultaneously with the new products, provide the current market volume, and the first- and fifth-year market projections for the predicate products in Table 1.

Table 1: Predicate Products: Current and Projected Market Volumes			
Predicate Product	**Current Market Volume (cans)**	**First-Year Projected Market Volume (cans)**	**Fifth-Year Projected Market Volume (cans)**
SE0014607			
SE0014608			
SE0014609			
SE0014610			
SE0014611			

2. All of your SE Reports lack detailed information about how the new products will be packaged. Packaging materials include plastic overwrap, retail boxes, and shipping cases. This information allows for an accurate assessment of the solid waste generated from use of the products. Address the following regarding packaging details of the new products and corresponding predicate products (if marketed simultaneously):

    a. Specify whether each can would be encased in a plastic overwrap, and if so, provide the weight (in grams) and composition (i.e., type of material) of the plastic overwrap.

b. Specify whether the cans would be packaged in a sleeve or retail box. If the cans are packaged in a sleeve, list the number of cans per sleeve and provide the weights (in grams) and composition of all packaging components. If the cans are packaged in a retail box, list the number of cans per retail box and provide the weight (in grams) and composition of the retail box.

c. Provide the number of cans per shipping case and the weight (in grams) and composition of the shipping case.

If the applicant adequately responds to the request and an EIS or FONSI is completed, SE order letters should be issued for the new tobacco products in SE0014607, SE0014608, SE0014609, SE0014610, and SE0014611 as identified on the cover page of this review.