

Technical Project Lead (TPL) Review:

SE0014579, SE0014582-SE0014585

SE0014579: Red Seal Fine Cut Wintergreen	
Package Type	Plastic Can and Lid
Package Quantity	42.53 g
Tobacco Cut Size ¹	(b)(4)
Characterizing Flavor	Wintergreen
SE0014582: Red Seal Long Cut Straight	
Package Type	Plastic Can and Lid
Package Quantity	42.53 g
Tobacco Cut Size ²	(b)(4)
Characterizing Flavor	None
SE0014583: Red Seal Long Cut Mint	
Package Type	Plastic Can and Lid
Package Quantity	42.53 g
Tobacco Cut Size ²	(b)(4)
Characterizing Flavor	Mint
SE0014584: Red Seal Long Cut Natural	
Package Type	Plastic Can and Lid
Package Quantity	42.53 g
Tobacco Cut Size ²	(b)(4)
Characterizing Flavor	None
SE0014585: Red Seal Long Cut Wintergreen	
Package Type	Plastic Can and Lid
Package Quantity	42.53 g
Tobacco Cut Size ²	(b)(4)
Characterizing Flavor	Wintergreen

¹ The applicant states that the new and predicate tobacco products contain a tobacco base comprised of 80% (b)(4) and 20% (b)(4)

² The applicant states that the new and predicate tobacco products contain a tobacco base comprised of 29.91% (b)(4) and 70.09% (b)(4)

Common Attributes of SE Reports	
Applicant	US Smokeless Tobacco Company
Report Type	Regular
Product Category	Smokeless Tobacco Product
Product Sub-Category	Loose Moist Snuff
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Todd L. Cecil -S Digitally signed by Todd L. Cecil -S Date: 2018.06.13 08:23:38 -04'00'

Todd L. Cecil, Ph.D.
Associate Director
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: 2018.06.13 11:21:40 -04'00'

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:

SE0014579: Red Seal Fine Cut Wintergreen	
Product Name	Red Seal Fine Cut Wintergreen
Package Type	Plastic Can and Lid
Package Quantity	42.53 g
Tobacco Cut Size ¹	(b)(4)
Characterizing Flavor	Wintergreen
SE0014582: Red Seal Long Cut Straight	
Product Name	Red Seal Long Cut Straight
Package Type	Plastic Can and Lid
Package Quantity	42.53 g
Tobacco Cut Size ²	(b)(4)
Characterizing Flavor	None
SE0014583: Red Seal Long Cut Mint	
Product Name	Red Seal Long Cut Mint
Package Type	Plastic Can with Lid
Package Quantity	42.53 g
Tobacco Cut Size ²	(b)(4)
Characterizing Flavor	Mint
SE0014584: Red Seal Long Cut Natural	
Product Name	Red Seal Long Cut Natural
Package Type	Plastic Can and Lid
Package Quantity	42.53 g
Tobacco Cut Size ²	(b)(4)
Characterizing Flavor	None
SE0014585: Red Seal Long Cut Wintergreen	
Product Name	Red Seal Long Cut Wintergreen
Package Type	Plastic Can and Lid
Package Quantity	42.53 g
Tobacco Cut Size ²	(b)(4)
Characterizing Flavor	Wintergreen

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 15, 2018, FDA received five SE Reports from Altria Client Services Inc (ALCS) on behalf of US Smokeless Tobacco Company LLC (USSTC). FDA Issued Acknowledgement letters to the applicant on March 22, 2018. FDA will issue an Advice/Information Request (A/I) letter to request information needed to compose an Environmental Assessment.

Product Name	SE Report
Red Seal Fine Cut Wintergreen	SE0014579
Red Seal Long Cut Straight	SE0014582
Red Seal Long Cut Mint	SE0014583
Red Seal Long Cut Natural	SE0014584
Red Seal Long Cut Wintergreen	SE0014585

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 Lauren DeBerry on March 22, 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 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 May 4, 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.³

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.

³ Addendum reviews were completed on May 14, 2018, to clarify the package quantity for the predicate tobacco products. Since the initial grandfather determination on May 4, 2018, was based on a product of that package quantity, the addendum reviews do not change the conclusion of the initial determination.

4. SCIENTIFIC REVIEW

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

4.1. CHEMISTRY

A chemistry review was completed by Abdur-Rafay Shareef on May 2, 2018.

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

- (b)(4) (non-GRAS) replaced with equal amount of (b)(4) (GRAS)

The applicant provided a certification statement signed by a responsible official authorized to act on behalf of the applicant stating that “the characteristics of the new and predicate product are identical in all aspects with the exception... replacement of non-GRAS (b)(4) in the predicate product with an identical amount of GRAS (b)(4) in the new product...” The only modification between the new and corresponding predicate products is the change in the flavor ingredient, non-GRAS (b)(4) to a GRAS (b)(4) with the exact same quantity (b)(4) mg/gram). Because the ingredient is going from non-GRAS to GRAS, the toxicity of the new products is expected to be no worse than the corresponding predicate products. Therefore, the difference in characteristics between the new and corresponding predicate tobacco products does not cause the new tobacco products to raise different questions of public health related to product composition.

5. ENVIRONMENTAL DECISION

An environmental science review was completed by Mehran Niazi on June 11, 2018.

The final environmental review found that information regarding how the new and predicate products will be packaged was not provided, the marketing intention of the new and predicate product was not provided, and the Synthetic Minor Air Pollutant Source Operating Permit was expired. 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 is the only difference in characteristics between the new and corresponding predicate tobacco products:

- (b)(4) (non-GRAS) replaced with equal amount of (b)(4) (GRAS)

The applicant has demonstrated that this difference in characteristics do not cause the new tobacco products to raise different questions of public health. The applicant provided a certification statement signed by a responsible official authorized to act on behalf of the applicant stating that

“the characteristics of the new and predicate product are identical in all aspects with the exception... replacement of non-GRAS (b)(4) in the predicate product with an identical amount of GRAS (b)(4) in the new product...” The only modification between the new and corresponding predicate products is the change in the flavor ingredient, non-GRAS (b)(4) to a GRAS (b)(4) with the exact same quantity (b)(4) mg/gram). Because the ingredient is going from non-GRAS to GRAS, the toxicity of the new products is expected to be no worse than the corresponding predicate products. 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, the chemistry review concludes 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 lack information regarding the marketing status of the predicate products. Marketing information will be used to evaluate the environmental impacts of use and disposal of the new products as compared to the corresponding predicate products. Provide the following information:
 - a. Identify if the predicate products will be concurrently marketed with the new products after receiving marketing orders.
 - b. If the predicate products are marketed concurrently with the new products, specify the current market volume (if currently marketed) and the first- and fifth-year market projections for the predicate products in Table 1.

Table 1: Market Volumes for Predicate Products				
STN	Unit	Current Market Volume	First-Year Projected Market Volume	Fifth-Year Projected Market Volume
GF1200203	Cans			
GF1200206	Cans			
GF1200204	Cans			
GF1200205	Cans			
GF1200207	Cans			

2. All of your SE Reports lack detailed information about how the new and corresponding predicate products will be packaged. The required information includes display boxes that contain

multiple cans and any other packaging materials. This information allows for an accurate assessment of the solid waste generated from disposal of the products. Answer the following questions:

- a. How is each retail unit packaged; are the cans packaged in a box; how many cans are packaged in a retail box; and how many retail boxes are in a shipping case?
- b. What is the material composition and weight of each packaging component of the new and corresponding predicate products (Table 2)?

Table 2: Packaging Weight for New and Predicate Products			
STN	Package Component	Package Composition	Weight (grams)
SE0014579	Shrink Wrap		
	Retail Box		
	Shipping Case		
SE0014582	Shrink Wrap		
	Retail Box		
	Shipping Case		
SE0014583	Shrink Wrap		
	Retail Box		
	Shipping Case		
SE0014584	Shrink Wrap		
	Retail Box		
	Shipping Case		
SE0014585	Shrink Wrap		
	Retail Box		
	Shipping Case		
GF1200203	Shrink Wrap		
	Retail Box		
	Shipping Case		
GF1200206	Shrink Wrap		
	Retail Box		
	Shipping Case		
GF1200204	Shrink Wrap		
	Retail Box		
	Shipping Case		
GF1200205	Shrink Wrap		
	Retail Box		
	Shipping Case		
GF1200207	Shrink Wrap		
	Retail Box		
	Shipping Case		

3. All of your SE Reports indicate that the Synthetic Minor Air Pollutant Source Operating Permit expired on December 31, 2017. A current permit allows a proper assessment of the status of air pollutant sources. Provide a current unexpired permit.

If the applicant adequately responds to these requests and an EIS or FONSI is completed, SE order letters should be issued for the new tobacco products in SE0014579, SE0014582-SE0014585, as identified on the cover page of this review.