

Technical Project Lead (TPL) Review: SE0015157 - SE0015176

SE0015157: Copenhagen Long Cut Black	
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) Cuts Per Inch (CPI)
Characterizing Flavor	None
SE0015158: Husky Fine Cut Natural	
Package Type	Plastic Can and Plastic Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) and (b) (4) CPI ¹
Characterizing Flavor	None
SE0015159: Red Seal Fine Cut Natural	
Package Type	Plastic Can and Plastic Lid
Package Quantity	42.53 grams
Tobacco Cut Size	(b) (4) and (b) (4) CPI ²
Characterizing Flavor	None
SE0015160: Husky Fine Cut Wintergreen	
Package Type	Plastic Can and Plastic Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) and (b) (4) CPI ¹
Characterizing Flavor	Wintergreen
SE0015161: Husky Long Cut Natural	
Package Type	Plastic Can and Plastic Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) and (b) (4) CPI ³
Characterizing Flavor	None
SE0015162: Husky Long Cut Straight	
Package Type	Plastic Can and Plastic Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) and (b) (4) CPI ³
Characterizing Flavor	None

¹ 80% at (b) (4) CPI and 20% at (b) (4) CPI

² 67.2% at (b) (4) CPI and 32.8% at (b) (4) CPI

³ 70.09% at (b) (4) CPI and 29.91% at (b) (4) CPI

SE0015163: Red Seal Long Cut Mint	
Package Type	Plastic Can and Plastic Lid
Package Quantity	42.53 grams
Tobacco Cut Size	(b) (4) and (b) (4) CPI ³
Characterizing Flavor	Mint
SE0015164: Red Seal Fine Cut Wintergreen	
Package Type	Plastic Can and Plastic Lid
Package Quantity	42.53 grams
Tobacco Cut Size	(b) (4) and (b) (4) CPI ¹
Characterizing Flavor	Wintergreen
SE0015165: Red Seal Long Cut Natural	
Package Type	Plastic Can and Plastic Lid
Package Quantity	42.53 grams
Tobacco Cut Size	(b) (4) and (b) (4) CPI ³
Characterizing Flavor	None
SE0015166: Red Seal Long Cut Straight	
Package Type	Plastic Can and Plastic Lid
Package Quantity	42.53 grams
Tobacco Cut Size	(b) (4) and (b) (4) CPI ³
Characterizing Flavor	None
SE0015167: Skoal Bandits Wintergreen	
Package Type	Plastic Can with Metal Lid
Package Quantity	13.90 grams
Portion Count	20 Portions
Portion Mass	694.7 mg/Portion
Portion Length	35 millimeters (mm)
Portion Width	16 mm
Portion Thickness	3.54 mm
Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	Wintergreen
Additional Property	Fine cut
SE0015168: Red Seal Long Cut Wintergreen	
Package Type	Plastic Can and Plastic Lid
Package Quantity	42.53 grams
Tobacco Cut Size	(b) (4) and (b) (4) CPI ³
Characterizing Flavor	Wintergreen
SE0015169: Skoal Fine Cut Original Wintergreen	
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 grams

Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	Wintergreen
SE0015170: Skoal Long Cut Classic Mint	
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	Mint
SE0015171: Skoal Long Cut Classic Straight	
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	None
SE0015172: Skoal Long Cut Berry Tobacco Blend	
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	Berry
SE0015173: Skoal Long Cut Cherry Tobacco Blend	
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	Cherry
SE0015174: Skoal Long Cut Classic	
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	None
SE0015175: Skoal Long Cut Spearmint Tobacco Blend	
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	Spearmint

SE0015176: Skoal Long Cut Classic Wintergreen	
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	Wintergreen
Common Attributes of SE Reports	
Applicant	U.S. Smokeless Tobacco Company LLC
Report Type	Regular
Product Category	Smokeless Tobacco Product
Product Sub-Category	Portioned and Loose Moist Snuff
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Jeannie H. Jeong-im -S
Date: 2019.06.19 14:55:17 -04'00'

Jeannie Jeong-Im, 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: 2019.06.19 15:16:14 -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:

SE0015157: Copenhagen Long Cut Black	
Product Name	Copenhagen Long Cut Black
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	None
SE0015158: Husky Fine Cut Natural	
Product Name	Husky Fine Cut Natural
Package Type	Plastic Can and Plastic Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) and (b) (4) CPI ¹
Characterizing Flavor	None
SE0015159: Red Seal Fine Cut Natural	
Product Name	Red Seal Fine Cut Natural
Package Type	Plastic Can and Plastic Lid
Package Quantity	42.53 grams
Tobacco Cut Size	(b) (4) and (b) (4) CPI ²
Characterizing Flavor	None
SE0015160: Husky Fine Cut Wintergreen	
Product Name	Husky Fine Cut Wintergreen
Package Type	Plastic Can and Plastic Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) and (b) (4) CPI ¹
Characterizing Flavor	Wintergreen
SE0015161: Husky Long Cut Natural	
Product Name	Husky Long Cut Natural
Package Type	Plastic Can and Plastic Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) and (b) (4) CPI ³
Characterizing Flavor	None

SE0015162: Husky Long Cut Straight	
Product Name	Husky Long Cut Straight
Package Type	Plastic Can and Plastic Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) and (b) (4) CPI ³
Characterizing Flavor	None
SE0015163: Red Seal Long Cut Mint	
Product Name	Red Seal Long Cut Mint
Package Type	Plastic Can and Plastic Lid
Package Quantity	42.53 grams
Tobacco Cut Size	(b) (4) and (b) (4) CPI ³
Characterizing Flavor	Mint
SE0015164: Red Seal Fine Cut Wintergreen	
Product Name	Red Seal Fine Cut Wintergreen
Package Type	Plastic Can and Plastic Lid
Package Quantity	42.53 grams
Tobacco Cut Size	(b) (4) and (b) (4) CPI ¹
Characterizing Flavor	Wintergreen
SE0015165: Red Seal Long Cut Natural	
Product Name	Red Seal Long Cut Natural
Package Type	Plastic Can and Plastic Lid
Package Quantity	42.53 grams
Tobacco Cut Size	(b) (4) and (b) (4) CPI ³
Characterizing Flavor	None
SE0015166: Red Seal Long Cut Straight	
Product Name	Red Seal Long Cut Straight
Package Type	Plastic Can and Plastic Lid
Package Quantity	42.53 grams
Tobacco Cut Size	(b) (4) and (b) (4) CPI ³
Characterizing Flavor	None

SE0015167: Skoal Bandits Wintergreen	
Product Name	Skoal Bandits Wintergreen
Package Type	Plastic Can with Metal Lid
Package Quantity	13.90 grams
Portion Count	20 Portions
Portion Mass	694.7 mg/Portion
Portion Length	35 mm
Portion Width	16 mm
Portion Thickness	3.54 mm
Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	Wintergreen
Additional Property	Fine cut
SE0015168: Red Seal Long Cut Wintergreen	
Product Name	Red Seal Long Cut Wintergreen
Package Type	Plastic Can and Plastic Lid
Package Quantity	42.53 grams
Tobacco Cut Size	(b) (4) and (b) (4) CPI ³
Characterizing Flavor	Wintergreen
SE0015169: Skoal Fine Cut Original Wintergreen	
Product Name	Skoal Fine Cut Wintergreen
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	Wintergreen
SE0015170: Skoal Long Cut Classic Mint	
Product Name	Skoal Long Cut Mint
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	Mint
SE0015171: Skoal Long Cut Classic Straight	
Product Name	Skoal Long Cut Straight
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	None

SE0015172: Skoal Long Cut Berry Tobacco Blend	
Product Name	Skoal Long Cut Berry Blend
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	Berry
SE0015173: Skoal Long Cut Cherry Tobacco Blend	
Product Name	Skoal Long Cut Cherry
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	Cherry
SE0015174: Skoal Long Cut Classic	
Product Name	Skoal Long Cut Classic
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	None
SE0015175: Skoal Long Cut Spearmint Tobacco Blend	
Product Name	Skoal Long Cut Spearmint
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	Spearmint
SE0015176: Skoal Long Cut Classic Wintergreen	
Product Name	Skoal Long Cut Wintergreen
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4) CPI
Characterizing Flavor	Wintergreen

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On April 1, 2019, FDA received twenty SE Reports from Altria Client Services LLC, on behalf of U.S. Smokeless Tobacco Company LLC. On April 8, 2019, FDA issued Acknowledgement letters to the applicant.

On April 22, 2019, FDA received an amendment (SE0015201) in response to a request from the Office of Compliance and Enforcement for SE0015157, SE0015159, SE0015163 - SE0015169, and SE0015175.

Product Name	SE Report	Amendments
Copenhagen Long Cut Black	SE0015157	SE0015201
Husky Fine Cut Natural	SE0015158	None
Red Seal Fine Cut Natural	SE0015159	SE0015201
Husky Fine Cut Wintergreen	SE0015160	None
Husky Long Cut Natural	SE0015161	
Husky Long Cut Straight	SE0015162	
Red Seal Long Cut Mint	SE0015163	SE0015201
Red Seal Fine Cut Wintergreen	SE0015164	
Red Seal Long Cut Natural	SE0015165	
Red Seal Long Cut Straight	SE0015166	
Skoal Bandits Wintergreen	SE0015167	
Red Seal Long Cut Wintergreen	SE0015168	
Skoal Fine Cut Original Wintergreen	SE0015169	
Skoal Long Cut Classic Mint	SE0015170	None
Skoal Long Cut Classic Straight	SE0015171	
Skoal Long Cut Berry Tobacco Blend	SE0015172	
Skoal Long Cut Cherry Tobacco Blend	SE0015173	
Skoal Long Cut Classic	SE0015174	
Skoal Long Cut Spearmint Tobacco Blend	SE0015175	SE0015201
Skoal Long Cut Classic Wintergreen	SE0015176	None

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 Lauren DeBerry on April 8, 2019.

The review concludes 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 product is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews dated May 1, 2019, May 2, 2019, and May 8, 2019 conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and, therefore, is an eligible predicate tobacco product.

OCE also completed a review to determine whether the new tobacco product is 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 reviews dated May 23, 2019, and June 5, 2019, conclude 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 Jason Hsieh on May 21, 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:

- (b) (4) (GRAS, (b) (4) – (b) (4) mg/g in the finished product) is directly added as a replacement to the (b) (4) (Non-GRAS)
- Non-GRAS (b) (4) in the (b) (4) is replaced with an identical amount (b) (4) mg/g in the finished product) of (b) (4)
- (b) (4) is added to the (b) (4) (b) (4) mg/g in the finished product)
- (b) (4) is added to the (b) (4) mg/g in the finished product)
- Decrease of (b) (4) ³ mg/g of (b) (4) to the (b) (4)
- Decrease of (b) (4) ⁻³ mg/g of (b) (4) to the (b) (4)
- Decrease of (b) (4) ⁻⁴ mg/g of (b) (4) to the (b) (4)

The applicant only provided information on the ingredients in the (b) (4) and ingredients of (b) (4) (direct additive) in the new and predicate tobacco products. The applicant did not provide the functions of the ingredients and did not demonstrate the total changes in the (b) (4) did not influence harmful and potentially harmful constituents (HPHC) formation. However, the applicant provided a certification statement stating, “there is no other modification to the materials, ingredients, design features, heating source, or any other feature of the New Product.” Based on the applicant’s certification

statement, any differences will not significantly affect the HPHCs of the new products compared to the corresponding predicate products; therefore, the addition of (b) (4) and corresponding decrease of (b) (4), and addition of (b) (4) in the (b) (4), and change from non-GRAS to GRAS (b) (4) in new tobacco products do not cause the new tobacco products to raise different questions of public health.

4.2. MICROBIOLOGY

A microbiology review was completed by Prashanthi Mulinti on May 15, 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:

- Composition of the fermented tobacco component
 - Addition (b) (4) mg/g of (b) (4)
 - Addition (b) (4) mg/g of a preservative (b) (4)
 - Addition (b) (4) mg/g of GRAS (b) (4) to replace identical amount of non-GRAS (b) (4)
- Addition (b) (4) mg/g of GRAS (b) (4) to replace identical amount of non-GRAS (b) (4)

For each SE Report, the applicant provided a certification statement indicating that the new and corresponding predicate tobacco products differ in the additions of (b) (4), GRAS (b) (4) and (b) (4) to the new tobacco products. From a microbiology perspective, the small amounts of (b) (4) (b) (4) mg/g, and GRAS (b) (4) (b) (4) mg/g 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.

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Thomas Creaven on May 17, 2019 and June 3, 2019⁴.

A finding of no significant impact (FONSI) for SE0015157, SE0015160 – SE0015162, SE0015169⁵ – SE0015171, and SE0015176 was signed by Kimberly Benson, Ph.D. on May 17, 2019. The FONSI for these SE Reports was supported by an environmental assessment prepared by FDA on May 17, 2019.

⁴ A corrected review was completed on June 3, 2019 to correct a STN number in the deficiency.

⁵ For SE0015169, the environmental reviews, FONSI, and EA uses the abbreviation “WG” for “Wintergreen” for the new and predicate tobacco products.

The final environmental review found the applicant did not specify the current year market volumes of the predicate tobacco products for SE0015158, SE0015159, SE0015163 – SE0015168, and SE0015172 – SE0015175. Therefore, additional information is needed for these SE Reports to determine whether to prepare an Environmental Impact Statement (EIS) or FONSI.

6. CONCLUSION AND RECOMMENDATION

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

- Composition of the (b) (4) component
 - Addition (b) (4) mg/g of (b) (4)
 - Addition (b) (4) mg/g of a preservative, (b) (4)
 - Addition (b) (4) mg/g of GRAS (b) (4) to replace identical amount of non-GRAS (b) (4)
 - Decrease of (b) (4) mg/g of (b) (4) tobacco
 - Decrease of (b) (4) mg/g of (b) (4) tobacco
 - Decrease of (b) (4) mg/g of (b) (4) tobacco
- Addition (b) (4) mg/g of GRAS (b) (4) to replace identical amount of non-GRAS (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 (b) (4) tobacco added, (b) (4) tobaccos displaced, and (b) (4) added to the (b) (4) (b) (4) of the new products are minor and not expected to lead to detectable increases in HPHCs. Since the (b) (4) 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 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.

For SE0015157, SE0015160 – SE0015162, SE0015169 – SE0015171, and SE0015176, FDA examined the environmental effects of finding these new tobacco products substantially equivalent and made a finding of no significant impact.

For SE0015158, SE0015159, SE0015163 – SE0015168, and SE0015172 – SE0015175, 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.

SE order letters should be issued for the new tobacco products in SE0015157, SE0015160 – SE0015162, SE0015169 – SE0015171, and SE0015176, as identified on the cover page of this review.

An Advice/Information Request letter should be issued for SE0015158, SE0015159, SE0015163 – SE0015168, and SE0015172 – SE0015175 requesting the following information:

Your SE Reports lack the current year market volumes of the predicate products that you stated are currently marketed. Marketing information is used to quantitatively assess the environmental impacts of manufacturing, use, and disposal of the new products as compared to the corresponding predicate products. Provide the current year market volume for the products listed in Table 1. Express your answer in number of cans and metric tons.

Table 1. Current Market Volume of Predicate Products				
New Product STN	Predicate Product STN	Predicate Product Name	Unit	Current Year Market Volume
SE0015158	GF1200196	Husky Fine Cut Natural	Cans	
			Metric Tons	
SE0015159	GF1200202	Red Seal Fine Cut Natural	Cans	
			Metric Tons	
SE0015163	GF1200204	Red Seal Long Cut Mint	Cans	
			Metric Tons	
SE0015164	GF1200203	Red Seal Fine Cut Wintergreen	Cans	
			Metric Tons	
SE0015165	GF1200205	Red Seal Long Cut Natural	Cans	
			Metric Tons	
SE0015166	GF1200206	Red Seal Long Cut Straight	Cans	
			Metric Tons	
SE0015167	GF1200212	Skoal Bandits Wintergreen	Cans	
			Metric Tons	
SE0015168	GF1200207	Red Seal Long Cut Wintergreen	Cans	
			Metric Tons	
SE0015172	GF1200217	Skoal Long Cut Berry Blend	Cans	
			Metric Tons	
SE0015173	GF1200218	Skoal Long Cut Cherry	Cans	
			Metric Tons	
SE0015174	GF1200219	Skoal Long Cut Classic	Cans	
			Metric Tons	
SE0015175	GF1200222	Skoal Long Cut Spearmint	Cans	
			Metric Tons	

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 SE0015158, SE0015159, SE0015163 – SE0015168, and SE0015172 – SE0015175, as identified on the cover page of this review.