

Technical Project Lead (TPL) Review: SE0013345 – SE0013346

SE0013345: Husky Long Cut Wintergreen	
Package Type	Plastic Can and Lid
Package Quantity	204.12 grams (g)
Tobacco Cut Size	(b) (4) CPI ¹
Characterizing Flavor ²	Wintergreen
SE0013346: Husky Long Cut Wintergreen	
Package Type	Plastic Can and Lid
Package Quantity	408.24 g
Tobacco Cut Size	(b) (4) CPI ¹
Characterizing Flavor ²	Wintergreen
Common Attributes of SE Reports	
Applicant	U.S. Smokeless Tobacco Company LLC
Report Type	Regular Product Quantity Change
Product Category	Smokeless Tobacco
Product Sub-Category	Loose Moist Snuff
Recommendation	
Issue Substantially Equivalent (SE) orders.	

¹ CPI – cuts per inch; the applicant states that (b) (4) (b) (4) CPI

² As provided by the applicant's certification statement. For product quantity change SE Reports, FDA does not conduct substantive scientific review to evaluate the information contained in the applicant's certification statement.

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2020.05.19 16:34:07 -04'00'

Colleen K. Rogers, Ph.D.
Director
Division of Product Science
Office of 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: 2020.05.19 16:38:45 -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:

SE0013345: Husky Long Cut Wintergreen	
Product Name	Husky Long Cut Wintergreen
Package Type	Plastic Can and Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b) (4) CPI ¹
Characterizing Flavor ²	Wintergreen
SE0013346: Husky Long Cut Wintergreen	
Product Name	Husky Long Cut Wintergreen
Package Type	Plastic Can and Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b) (4) CPI ¹
Characterizing Flavor ²	Wintergreen

The applicant submitted the same predicate tobacco product for both new tobacco products. The predicate tobacco product is a loose moist snuff tobacco product manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On May 4, 2016, FDA received two Product Quantity Change (PQ) SE Reports (SE0013345-SE0013346) from Altria Client Services LLC, on behalf of U.S. Smokeless Tobacco Company LLC. On May 23, 2016, FDA issued an Acknowledgment letter. On May 25, 2016, FDA received an amendment (SE0013394) containing additional information to identify the new and predicate tobacco products requested in a teleconference dated May 24, 2016. On April 6, 2017, FDA received an amendment (SE0014017) containing clarification of the package format requested in a teleconference dated March 31, 2017. FDA issued an Advice/Information (A/I) Request letter to the applicant on February 26, 2018, to inform the applicant that scientific review will commence once a final order has been issued for the predicate tobacco product (a pending provisional SE Report) referenced in the original submission. On March 20, 2020, FDA received an amendment (SE0015783) providing unique Environmental Assessments for each new tobacco product as requested in a teleconference dated March 9, 2020.

Product Name	SE Report	Amendments
Husky Long Cut Wintergreen	SE0013345	SE0013394 SE0014017
Husky Long Cut Wintergreen	SE0013346	SE0015783

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 Angela Brown on May 20, 2016, and Arielle Patno on February 26, 2018.

The final reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco products in SE0013345 – SE0013346 were determined to be substantially equivalent by FDA under SE0000499. Therefore, the predicate tobacco product is an eligible predicate tobacco product.

The Office of Compliance and Enforcement (OCE) completed reviews 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 reviews dated January 9, 2018, and May 11, 2020, conclude that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

A scientific review was completed by the Office of Science (OS) for the following discipline:

4.1. SOCIAL SCIENCE

A social science review was completed by Anh Nguyen on August 2, 2016.

The review identified the following differences between the new and predicate tobacco products:

- SE0013345: 500% increase in product quantity
- SE0013346: 1100% increase in product quantity

The social science review concludes that the new tobacco products have different characteristics from the predicate tobacco product and that the SE Reports lack adequate evidence to demonstrate that the differences do not cause the new tobacco products to raise different questions of public health from a social science perspective. However, since the time the social science review was finalized, OS prepared a memorandum³ summarizing its current thinking on product quantity changes. With respect to product quantity increases, the currently available scientific evidence examines the effects of product quantity in other consumer products on consumer behavior and perception but is not specific to tobacco products generally or the specific category of tobacco product under social science review. This evidence suggests that changes in product quantity of consumer products may influence consumer behavior but was not specific enough for OS to determine if such changes always lead to changes in behavior, and, if not, under what condition it would; what threshold (if any) would trigger a change in consumer behavior; what tobacco products would be affected by a quantity change and which would not; and how findings about consumer behavior and use of other consumer products may

³ See memorandum on product quantity changes, dated December 7, 2017.

translate to tobacco use intention and behavior. Thus, based upon the currently available science and CTP’s experience in reviewing SE Reports, from a social science perspective, product quantity changes do not cause new tobacco products to raise different questions of public health. Consequently, the changes in product quantity do not cause the new tobacco products to raise different questions of public health from a social science perspective.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Ronald Edwards on April 6, 2020.

A finding of no significant impact (FONSI) was signed by Luis Valerio for Kimberly Benson on April 20, 2020. The FONSI was supported by an environmental assessment prepared by FDA on April 20, 2020.

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and predicate tobacco products are identical except for the following:

- SE0013345: 500% increase in product quantity
- SE0013346: 1100% increase in product quantity

The OS memorandum,³ which is more recent than the social science review, concludes that based on OS’s experience and the currently available evidence, the difference in product quantity does not cause the new tobacco products to raise different questions of public health. I concur with this conclusion.

The predicate tobacco products in SE0013345 – SE0013346 were determined to be substantially equivalent by FDA under SE0000499.

Where an applicant supports a showing of SE by comparing the new tobacco product to a tobacco product that FDA previously found SE, in order to issue an SE order, FDA must find that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act).

The predicate tobacco product in SE0013345 – SE0013346 was previously determined to be substantially equivalent by FDA under SE0000499. Comparison of the new tobacco products to the grandfathered product (Husky Long Cut Wintergreen) reveals that the new tobacco products have the following differences in characteristics from the grandfathered tobacco product:

- SE0013345 only: 500% increase in product quantity
- SE0013346 only: 1100% increase in product quantity
- Addition of (b) (4) mg/g)
- 2.4% decrease in (b) (4) 5.1% decrease in (b) (4), and 4.4% decrease in (b) (4)
- 42% decrease in (b) (4)
- Addition of (b) (4) as a preservative (b) (4) mg/g)

- Addition of (b) (4) mg/g)
- Addition of (b) (4) mg/g)
- 24% increase in free nicotine
- (b) (4) increase in tobacco cut size (CPI)
- Decreases in NNN ($\leq 37\%$), NNK ($\leq 58\%$), and tobacco-specific nitrosamines (38%) over the shelf life
- Decreases in total (b) (4) ($\leq 60\%$) over the shelf life

The differences in characteristics listed above, other than the differences in product quantity, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0000499. Therefore, these differences do not cause the new tobacco products in SE0013345 – SE0013346 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in product quantity between the new tobacco products in SE0013345 – SE0013346 and the grandfathered tobacco product do not cause the new tobacco products to raise different questions of public health. Therefore, whether comparing the new tobacco products in SE0013345 – SE0013346 to the predicate or grandfathered tobacco product, the new tobacco products do not raise different questions of public health.

The new tobacco products are currently in compliance with the FD&C Act.

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 SE0013345 – SE0013346, as identified on the cover page of this review.