FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0001910 & SE0001916

SE0001910: Kayak Fine Cut Natural	
Package Type	Can
Package Quantity	34.02 g
Tobacco Cut Size	(b) (4) mm
Characterizing Flavor	Natural
SE0001916: Kayak Long Cut Wintergreen	
Package Type	Can
Package Quantity	34.02 g
Tobacco Cut Size	(b) (4) mm
Characterizing Flavor	Wintergreen
Common Attributes of SE Reports	
Applicant	Swisher International, Inc.
Report Type	Provisional
Product Category	Smokeless Tobacco
Product Sub-Category	Loose Moist Snuff
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

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Date: 2018.04.30 12:02:37 -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 Matthew R. Holman -S
Date: 2018.04.30 12:41:46 -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:

SE0001910: Kayak Fine Cut Natural	
Product Name	Redwood Fine Cut
Package Type	Can
Package Quantity	34.02 g
Tobacco Cut Size	(b) (4) mm
Characterizing Flavor	Natural
SE0001916: Kayak Long Cut Wintergreen	
Product Name	Kayak Long Cut Wintergreen
Package Type	Can
Package Quantity	34.02 g
Tobacco Cut Size	(b) (4) mm
Characterizing Flavor	Wintergreen

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 21, 2011, Swisher International Inc. submitted two provisional Substantial Equivalence (SE) Reports (SE0001910 and SE0001916). FDA acknowledged the SE Reports on August 30, 2011. On July 10, 2012, the applicant submitted unsolicited amendments (SE0004678 and SE0004684) containing environmental assessments. FDA issued an Advice/Information Request (A/I) letter on April 29, 2013. In response, the applicant submitted amendments (SE0008599 and SE0008603) on May 20, 2013. On September 12, 2013, FDA conducted a telecon to request the applicant provide additional packaging information. In response, the applicant submitted an amendment (SE0009803) on September 16, 2013. On October 7, 2013, and October 8, 2013, the applicant submitted unsolicited amendments (SE0009888 and SE0009894) providing documentation of the predicate tobacco product grandfathered status for SE0001910 and SE0001916, respectively.

On August 11, 2015, FDA notified the applicant that their pending provisional SE Reports would be subject to scientific review beginning September 25, 2015. In response, the applicant submitted amendment (SE0012388) containing additional information on September 24, 2015. FDA issued an A/I Letter on April 29, 2016. On May 20, 2016, the applicant submitted an amendment (SE0013367) requesting a 7-month extension to respond to the April 29, 2016 A/I letter. On June 6, 2016, FDA issued an Extension Granted letter with a response due date of January 28, 2017. On January 27, 2017, the applicant submitted amendment (SE0013847). FDA issued a Preliminary Finding (Pfind) letter on May 31, 2017. In response to the Pfind letter, the applicant submitted an amendment (SE0014189) on June 29, 2017.

Product Name	SE Report	Amendments
Kayak Fine Cut Natural	SE0001910	SE0004678 SE0008599 SE0009803 SE0009888 SE0012388 SE0013367 SE0013847 SE0014189
Kayak Long Cut Wintergreen	SE0001916	SE0004684 SE0008603 SE0009803 SE0009894 SE0012388 SE0013367 SE0013847 SE0014189

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 Marcella White on August 31, 2011, by Stephanie Durkin on April 29, 2013, and by Lauren DeBerry on August 17, 2017.

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 as of February 15, 2007). The OCE review dated April 26, 2018 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.

4. SCIENTIFIC REVIEW

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

4.1. CHEMISTRY

Chemistry reviews were completed by An Vu on November 20, 2015, and by Andre Williams on March 23, 2017 and August 14, 2017.

The final 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:

- Lower total amount of tobacco ([redacted]/g product) compared to the predicate product [redacted]/g product) in the new tobacco product of SE0001910
- Addition of [redacted] in the new tobacco product for SE0001910
- Removal of [redacted] from the new tobacco product in SE0001910
- Higher amounts of [redacted] in the new tobacco product for SE0001910
- Replacement of [redacted] in the new tobacco product for SE0001910
- Replacement of [redacted] with an equal amount of [redacted] in the new tobacco product for SE0001916

The review concludes that most changes in flavor quantities in SE0001910 are minuscule amounts ([redacted]/g) and do not cause the new tobacco products to raise different questions of public health because their amounts are negligible. The new tobacco product contains higher quantities ([redacted]) of flavor ingredients ([redacted]) and the introduction of flavor ingredients ([redacted]). The applicant identified these ingredients, and subcomponents of complex ingredients, as generally recognized as safe (GRAS). However, GRAS status is established only for ingredients in food products, and not for ingredients used in tobacco products. However, since these ingredients are intended for use in food which is ingested by consumers, their presence in a smokeless tobacco product won't affect consumers if they are similarly absorbed or ingested. For SE0001916, the new product replaces [redacted] that is used in the predicate product with an identical amount of [redacted]. The applicant identified these ingredients, and subcomponents of complex ingredients, as generally regarded as safe. These ingredients are present at low levels ([redacted]/product) and therefore do not cause the new product to raise different questions of public health[1]. In totem, the minimal changes in tobacco blends and ingredients and statistically equivalent HPHC measurements

[1] The chemistry review erroneously deferred evaluation of flavoring ingredients to social science to determine whether the addition of flavoring ingredients in the new product caused the product to raise different questions of public health, however, social science was not included as part of the scientific discipline review. Chemistry has adequately evaluated the changes in flavor differences and has determined that the changes in flavor ingredients between the new and corresponding predicate products do not cause the new tobacco products to raise different questions of public health.

between the new and predicate tobacco products do not cause the new products to raise different questions of public health.

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 related to product composition.

4.2. ENGINEERING

Engineering reviews were completed by Ouided Rouabhi on November 18, 2015, and by Aarthi Arab on March 13, 2017.

The final engineering 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 an engineering perspective. 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 related to product engineering.

4.3. MICROBIOLOGY

Microbiology reviews were completed by Almaris Alonso on December 18, 2015, and by David Craft on March 21, 2017.

The final 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 related to product microbiology:

- Decreases in water activity, NNN and NNK levels over the shelf life
- Increase in two preservatives ([redacted]) and removal of two preservatives ([redacted]) in the new tobacco product for SE0001910
- Change in concentration of humectants in the new tobacco product for SE0001910

The microbial differences between the new and predicate tobacco products were assessed based on water activity (a_w) data and NNK and NNN amounts. All a_w measurements showed very little variation ([redacted]) between the new and corresponding predicate products in each SE Report. In addition, for both new tobacco products, the a_w measurements were stable and decreased very slightly ([redacted]) over the storage time of the product. For the new tobacco product in SE0001910, both NNN (≤20%) and NNK (≤16%) levels decreased during the storage time of the product, which is comparable to the decrease in NNN (≤24%) and NNK (≤25%) levels of the predicate tobacco product. In addition, the new tobacco product in comparison to the predicate product showed only slight variation in NNN and NNK levels at the beginning (≤10%), middle (≤1%) and end (≤4%) of the storage time of the products. Based on the a_w, NNN and NNK data,

the changes in the humectants and preservatives of the new product are not of concern from a microbiology perspective and do not cause the new tobacco product to raise different questions of public health.

For the new tobacco product in SE0001916, NNN (≤56%) and NNK (≤93%) levels increased during the storage time of the product. However, these increases were less than the increases in NNN (≤68%) and NNK (≤102%) levels for the predicate tobacco product, which does not cause the new tobacco product to raise different questions of public health. In addition, the new tobacco product showed little variation in NNN and NNK levels at the beginning (≤7%), middle (≤5%) and end (<1%) of the product storage time. From a microbiology perspective, based on the a_w, NNN and NNK data for the new tobacco product in SE0001916, the addition of water (as humectant) and lack of preservatives in the new tobacco product are not of concern and do not cause the new tobacco product to raise different questions of public health.

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.

4.4. TOXICOLOGY

Toxicology reviews were completed by Sang Ki Park on January 25, 2016, and by Mary Irwin on May 1, 2017, and August 14, 2017.

The final toxicology 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 toxicology perspective. 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 related to product toxicology.

4.5. BEHAVORIAL AND CLINCIAL PHARMACOLOGY

A behavioral and clinical pharmacology review was completed by Kia Jackson on March 20, 2017.

The final behavioral and clinical pharmacology 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 behavioral and clinical pharmacology perspective. 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 related to consumer use of the product and impact on exposure and behavior.

5. ENVIRONMENTAL DECISION

Under 21 CFR 25.35(a), issuance of SE orders under section 910(a) of the FD&C Act for these provisional SE Reports is categorically excluded and, therefore, normally does not require the preparation of an environmental assessment (EA) or an environmental impact statement. FDA has

considered whether there are extraordinary circumstances that would require the preparation of an EA and has determined that none exist.

6. CONCLUSION AND RECOMMENDATION

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

- Lower total amount of tobacco ([redacted]/g product) compared to the predicate product ([redacted]/g product) in the new tobacco product of SE0001910
- Addition of [redacted] in the new tobacco product for SE0001910
- Removal of [redacted] from the new tobacco product in SE0001910
- Higher amounts of [redacted] in the new tobacco product for SE0001910
- Replacement of [redacted] in the new tobacco product for SE0001910
- Replacement of [redacted] with an equal amount of [redacted] in the new tobacco product for SE0001916
- Differences in water activity, NNN and NNK levels over the shelf life
- Increase in two preservatives ([redacted]) and removal of two preservatives ([redacted]) for the new tobacco product in SE0001910 only
- Change in concentration of humectants in the new tobacco product for SE0001910 only

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The new and predicate product have differences in the amount of tobacco blends and ingredient. The applicant provided HPHC data in which the differences in HPHC quantities of the new tobacco products are statistically equivalent and within the analytical variability of the measurements. Therefore, these differences in characteristics do not cause the new tobacco products to raise different questions of public health. Furthermore, the applicant provided stability data on the new and predicate tobacco products demonstrating through water activity, TSNA levels, and yeast and mold counts, that the shelf-life of the new tobacco products is comparable to that of their corresponding predicate tobacco product. 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 products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007.

All of the scientific reviews conclude that the differences between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health. I concur with the discipline reviews and recommend that SE order letters be issued.

Because the proposed action is issuing SE orders for these provisional SE Reports, it is a class of action that is categorically excluded under 21 CFR 25.35(a). FDA has considered whether there are extraordinary circumstances that would require the preparation of an environmental assessment and has determined that none exist. Therefore, the proposed action does not require preparation of an environmental assessment or an environmental impact statement.

SE order letters should be issued for the new tobacco products in SE0001910 & SE0001916, as identified on the cover page of this review.