FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0011094-SE0011096

SE0011094: Kayak Fine Cut Natural	
Package Type	Plastic tub and lid
Package Quantity	14.4 oz.
Tobacco Cut Size	(b)(4) [redacted]
Characterizing Flavor	Natural[1]
SE0011095: Kayak Long Cut Straight	
Package Type	Plastic tub and lid
Package Quantity	14.4 oz.
Tobacco Cut Size	(b)(4) [redacted]
Characterizing Flavor	Straight[1]
SE0011096: Kayak Long Cut Wintergreen	
Package Type	Plastic tub and lid
Package Quantity	14.4 oz.
Tobacco Cut Size	(b)(4) [redacted]
Characterizing Flavor	Wintergreen[1]
Common Attributes of SE Reports	
Applicant	Swisher International, Inc.
Report Type	Regular
Product Category	Smokeless Tobacco Products
Product Sub-Category	Loose Moist Snuff
Recommendation	
Issue Substantially Equivalent (SE) orders.	

[1] As provided by the applicant's certification statement.

Technical Project Lead (TPL):

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Date: 2019.02.27 09:08:18 -05'00'

Colleen K. Rogers, Ph.D.
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: 2019.02.27 11:28:33 -05'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

TABLE OF CONTENTS

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0011094: Kayak Fine Cut Natural	
Product Name	Kayak Fine Cut Natural
Package Type	Plastic can and lid
Package Quantity	1.2 oz.
Tobacco Cut Size	(b)(4) [redacted]
Characterizing Flavor	Natural[1]
SE0011095: Kayak Long Cut Straight	
Product Name	Kayak Long Cut Straight
Package Type	Plastic can and lid
Package Quantity	1.2 oz.
Tobacco Cut Size	(b)(4) [redacted]
Characterizing Flavor	Straight[1]
SE0011096: Kayak Long Cut Wintergreen	
Product Name	Kayak Long Cut Wintergreen
Package Type	Plastic can and lid
Package Quantity	1.2 oz.
Tobacco Cut Size	(b)(4) [redacted]
Characterizing Flavor	Wintergreen[1]

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On April 2, 2015, FDA received three SE Reports from Swisher International, Inc. FDA issued Acknowledgement letters on April 23, 2015. On May 5, 2015, FDA contacted the applicant by email to request product identification information for the new and predicate tobacco products. On May 11, 2015, FDA received an amendment (SE0011750) containing the requested information. On February 13, 2017 and March 30, 2017, FDA conducted telecons to request revised certification statements and additional information on the packaging material used for the new and predicate tobacco products. FDA received the applicant's responses to the information requests on March 27, 2017 (SE0014007) and March 31, 2017 (SE0014012).

In the original applications, the applicant designated the reports as Product Quantity Change SE Reports, and included certification statements to reflect that the only difference between the new and corresponding predicate tobacco products is the product quantity change. During review, FDA found differences in the container-closure system composition between the new and corresponding predicate tobacco products in all SE Reports. Since the differences between the new and corresponding predicate tobacco products are not limited to a difference in product quantity, FDA reclassified the SE Reports from Product Quantity Change SE Reports to full SE Reports. On February 28, 2018, FDA issued an Advice/Information (A/I) Request letter requesting clarification of the composition of the container-closure systems and information

related to the environmental assessment.[2] On March 19, 2018, FDA received a request for an extension to respond to the A/I Request letter (SE0014587). On April 27, 2018, FDA granted the applicant an extension until November 29, 2018. On November 29, 2018, FDA received an amendment (SE0014988) responding to the A/I Request letter. In teleconferences held on January 8, 2019, and January 11, 2019, FDA requested clarification of packaging configurations and shipment/storage of product samples used for stability testing. On January 11, 2019 (SE0015050), and February 1, 2019 (SE0015077), FDA received responses to the requests for clarification of the packaging configurations and shipment/storage of product samples communicated on January 8 and January 17, 2019, respectively.

Product Name	SE Report	Amendments
Kayak Fine Cut Natural	SE0011094	SE0011750 SE0014007 SE0014587 SE0014988 SE0015050 SE0015077
Kayak Long Cut Straight	SE0011095	SE0011750 SE0014012 SE0014587 SE0014988 SE0015050 SE0015077
Kayak Long Cut Wintergreen	SE0011096	SE0011750 SE0014007 SE0014587 SE0014988 SE0015050 SE0015077

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 Grace Kaiyuan on April 23, 2015.

The reviews conclude that the SE Reports are administratively complete.

[2] See February 27, 2018, TPL memorandum, "Clarification regarding container closure systems of the new and predicate tobacco products in SE0011094 – SE0011096 and communication of appropriate deficiencies".

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the predicate tobacco product in SE0011095 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 review dated June 12, 2015, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product in SE0011095 is grandfathered and, therefore, is an eligible predicate tobacco product.[3]

On April 30, 2018, the predicate tobacco products in SE0011094 and SE0011096 were determined to be substantially equivalent by FDA under SE0001910 and SE0001916, respectively. Therefore, these products are eligible predicate tobacco products.

OCE also 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 June 30, 2015; July 2, 2015;[4] January 11, 2018;[5] and February 14, 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 Selena Russell on January 23, 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:

- 1100% increase in product quantity
- Change in container-closure system from colored polypropylene can to white propylene-ethylene copolymer tub[6]

The applicant provided a list of ingredients in the container-closure systems (CCS) for the new and corresponding predicate tobacco products. The change in CCS from polypropylene to propylene-ethylene copolymer does not cause the new tobacco products to raise different

[3] An addendum review was completed on February 19, 2019, to clarify that the applicant identified the characterizing flavor of the predicate tobacco product is "Straight." The addendum review does not change the conclusion of the initial grandfather determination dated June 12, 2015.
[4] SE0011095 only
[5] SE0011094 and SE0011096 only
[6] The applicant indicates that an empty, small can with lid is shrink-wrapped to the outside of the new tobacco product (i.e., the plastic tub with lid that holds 14.4 oz of tobacco) and may be used to hold smaller quantities (1.2 oz) of tobacco. The applicant specified that the small empty can with lid attached to the new tobacco product is identical to the small can with lid in the corresponding predicate tobacco product.

questions of public health because both plastics have similar barrier properties to water and oxygen. In addition, the applicant submitted results from a 24-week stability study of the new and predicate tobacco products, which were stored in a controlled environment in their respective CCS[7] for the duration of the study. Total nicotine, pH, NNK, NNN, arsenic, cadmium, acetaldehyde, crotonaldehyde, and formaldehyde were measured at zero, 12, and 24 weeks. All constituent results are analytically equivalent or lower between the new and corresponding predicate tobacco products at zero weeks and all increases from zero to 24 weeks are comparable or lower in the new tobacco products than in the corresponding predicate tobacco products. 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. MICROBIOLOGY

A microbiology review was completed by Prashanthi Mulinti on January 22, 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:

- 1100% increase in product quantity
- Change in container-closure system

The applicant submitted stability testing data over 24 weeks of storage time for the new and corresponding predicate tobacco products.[7] The water activity (a_w) of all new tobacco products varied minimally (b) (4) compared to the corresponding predicate tobacco products at time zero and over the 24-week storage time of the stability study. Additionally, at the final timepoint, all new tobacco products showed lower levels of NNN (11 - 17%) and NNK (5 - 20%) when compared to the corresponding predicate tobacco products. When comparing the levels of NNN at the end of the study to time zero, NNN levels in all new tobacco products showed smaller increases when compared to the corresponding predicate tobacco products (21 vs 38% for SE0011094; 6 vs 27% for SE0011095; 4 vs 17% for SE0011096). Similarly, NNK levels from time zero until the end of the study showed smaller increases for all new tobacco products when compared to the corresponding predicate tobacco products (19 vs 26% for SE0011094; 2 vs 28% for SE0011095; 7 vs 33% for SE0011096). 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.

[7] Amendment SE0015077, which clarifies that the new tobacco products were stored in the new tobacco product container-closure system for the duration of the stability study, was not included in the review because the review was finalized before the amendment was received. However, the information in the amendment was conveyed via teleconference on January 17, 2019, prior to finalization of the review and, thus, was considered by the reviewer. The information in this amendment does not change the final conclusions of the review.

4.3. SOCIAL SCIENCE

A social science review was completed by Wendy Slavit on August 7, 2015.

The social science review concludes that the new tobacco products have different characteristics from the corresponding predicate tobacco products 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. The review identifies the following deficiencies that have *not* been adequately resolved:

1. All of your SE Reports indicate that the new product is being manufactured in a larger package quantity than the predicate product. There is a 1,100% increase in the package quantity between the predicate products and the new products (1.2 oz. vs 14.4 oz.). It is possible that introducing the product in various quantities may raise different questions of public health. For example, providing more tobacco in a single package may increase consumption and make it more difficult to quit.

   You submitted market data for your competitors' products, however you did not indicate the package quantity of the products analyzed. Without the package quantities identified, we are unable to assess whether your products are comparable to the products of your competitors for comparison. Furthermore, in order to assess the new products, we need more information about how the larger package quantity may impact public health. Submit any information that demonstrates that the differences in package quantity do not cause the new product to raise different questions of public health. This information may include, but is not limited to:

   - Consumer perception studies comparing attitudes, beliefs, and behavioral intentions for the new product to the predicate product
   - Market analyses (e.g., sales and/or market segmentation analyses to identify likely consumers of the new products)
   - Studies on purchasing frequency that demonstrate that the amount of product used per day or per week is similar between the predicate and new tobacco products
   - Other research and analyses conducted to prepare for the new products' introduction into the marketplace

2. All of your SE Reports indicate that the new products are being packaged plastic tubs, while the predicate products are packaged in plastic pocket cans. However, you did not provide information on how the package type (e.g., dimensions and shape) has changed compared to the predicate product. It is possible that marketing the new products in a different package type (e.g., dimensions and shape) than that for the predicate products may cause the new product to raise different questions of public health. In order to assess the new product, we need information about how the different package type impacts consumer perceptions, appeal, and use. Submit any information that

demonstrates that the different package types do not cause the new product to raise different questions of public health. This information may include but is not limited to:

- Consumer perception studies comparing attitudes, beliefs, and behavioral intentions for the new product to the predicate product
- Market analyses (e.g., sales and/or market segmentation analyses to identify likely consumers of the new products compared to those of the predicate products)
- Studies on purchasing frequency that demonstrate that the amount of product used per day or per week is similar between the predicate and new tobacco products
- Other research and analyses conducted to prepare for introduction of the new products into the marketplace

The review concludes that the applicant did not demonstrate that 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 social science perspective. I do not concur with this conclusion. All SE Reports indicate an 1100% increase in product quantity. Since the time that the social science review was finalized, OS prepared a memorandum[8] 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 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.

In the second social science deficiency, the change in "package type" referred to by the reviewer is actually a change to the container-closure system (CCS). The CCS, a subset of packaging, is a component or part of a tobacco product and thus can be reviewed through the SE process. Although a CCS's impact on the physical characteristics of the product may be relevant in assessing the appeal of a product in some circumstances, the review was not warranted for the shape change at issue in this case. The social science review was based on the change in shape of the CCS and how that shape change, by itself, might affect the appeal of the product, and the review did not identify changes to the product's performance, composition, constituents, or characteristics that could impact the appeal of the product.[9] Consequently, the change in CCS for the new tobacco products subject of this review do not cause the new tobacco products to

[8] See memorandum on product quantity changes, dated December 7, 2017.

[9] The chemistry and microbiology reviews assessed how differences in the CCS between the new and corresponding predicate tobacco products might affect the product's performance, composition, constituents, or characteristics (see sections 4.1 and 4.2 of this review).

raise different questions of public health from a social science perspective and deficiency 2 should not be conveyed to the applicant. 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 social science perspective.

The review also evaluated the health information summary for each SE Report. FDA has determined that the health information summary provided for these SE Reports would not cause a violation of section 911 of the FD&C Act upon introduction or delivery for introduction of the new tobacco products into interstate commerce.

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Shannon Hanna on January 26, 2018, and by Rudaina Alrefai-Kirkpatrick on January 4, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on February 27, 2019. The FONSI was supported by an environmental assessment prepared by FDA on February 27, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- 1100% increase in product quantity
- Change in container-closure system from colored polypropylene can to white propylene-ethylene copolymer tub

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The applicant submitted results from a 24-week stability study of the new and corresponding predicate tobacco products. The stability data show that chemical constituents (i.e., total nicotine, pH, NNK, NNN, arsenic, cadmium, acetaldehyde, crotonaldehyde, and formaldehyde) and microbial indicators (i.e., moisture, water activity) are stable and any changes over time are similar or smaller for the new tobacco product compared to the corresponding predicate tobacco product. All the SE Reports indicate an 1100% increase in product quantity. The OS memorandum[8] concludes that based on OS' 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. 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 product in SE0011095 meets statutory requirements because it was determined that it 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 predicate tobacco products in SE0011094 and SE0011096 were previously determined to be substantially equivalent by FDA under SE0001910 and SE0001916, respectively.

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 SE0011094 was previously determined to be substantially equivalent by FDA under SE0001910. Comparison of the new tobacco product to the grandfathered product (Redwood Fine Cut in SE0001910) reveals that the new tobacco product has the following differences in characteristics from Redwood Fine Cut, the grandfathered tobacco product:

- 1100% increase in product quantity
- Change in container-closure system from colored polypropylene can to white propylene-ethylene copolymer tub
- 2% decrease in total tobacco blend weight
- Addition of 1 (b)(4) [redacted]
- Removal of (b)(4) [redacted]
- Increases in (b)(4) [redacted], and (b)(4) [redacted]
- Replacement of (b) (4) [redacted]) with (b) (4) [redacted] (b) (4) [redacted])
- 15% increase in two preservatives (b)(4) [redacted] and removal of two preservatives (b)(4) [redacted]

The differences in characteristics listed above, other than the differences in product quantity and container-closure system, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0001910. Therefore, these differences do not cause the new tobacco product in SE0011094 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in product quantity and container-closure system between the new tobacco product in SE0011094 and the grandfathered tobacco product does not cause the new tobacco product to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0011094 to the predicate or grandfathered tobacco product, the differences between the new tobacco product and the predicate or grandfathered tobacco product do not cause the new tobacco product to raise different questions of public health.

The predicate tobacco product in SE0011096 was previously determined to be substantially equivalent by FDA under SE0001916. Comparison of the new tobacco product to the grandfathered product (Kayak Long Cut Wintergreen in SE0001916) reveals that the new tobacco product has the following differences in characteristics from Kayak Long Cut Wintergreen, the grandfathered tobacco product:

- 1100% increase in product quantity
- Change in container-closure system from colored polypropylene can to white propylene-ethylene copolymer tub
- Replacement of (b)(4) [redacted] with an equal amount of (b)(4) [redacted]

The replacement of (b)(4) [redacted] with an equal amount of (b)(4) [redacted] is the same difference in characteristics identified for the new and grandfathered tobacco products in SE0001916. Therefore, this difference does not cause the new tobacco product in SE0011096 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in product quantity and container-closure system between the new tobacco product in SE0011096 and the grandfathered tobacco product does not cause the new tobacco product to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0011096 to the predicate or grandfathered tobacco product, the differences between the new tobacco product and the predicate or grandfathered tobacco product do not cause the new tobacco product to raise different questions of public health.

The new tobacco products are currently in compliance with the FD&C Act. In addition, all of the scientific reviews except social science conclude that the differences between the new and corresponding predicate tobacco products are such that they do not cause the new tobacco products to raise different questions of public health. I do not concur with the social science review as discussed in section 4.3 of this review. I concur with the remaining reviews and recommend that SE order letters be issued.

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 SE0011094-SE0011096, as identified on the cover page of this review.