FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0014825 and SE0014826

SE0014825: Copenhagen Long Cut Straight	
Package Type	Plastic can and metal lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4)
Characterizing Flavor	None
SE0014826: Husky Long Cut Natural	
Package Type	Plastic can and metal lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4)
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	U.S. Smokeless Tobacco Company LLC
Report Type	Regular
Product Category	Smokeless Tobacco Products
Product Sub-Category	Loose Moist Snuff
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

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Date: 2018.10.22 14:54:58 -04'00'

Shixia Feng, 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: 2018.10.23 11:59:03 -04'00'

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:

SE0014825: Copenhagen Long Cut Straight	
Product Name	Copenhagen Long Cut Straight
Package Type	Fiberboard can and metal lid
Package Quantity	34.02 grams
Tobacco Cut Size	(b) (4)
Characterizing Flavor	None
SE0014826: 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)
Characterizing Flavor	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On July 25, 2018, FDA received two Substantial Equivalence (SE) Reports, from Altria Client Services LLC on behalf of U.S. Smokeless Tobacco Company LLC. FDA issued Acknowledgement letters to the applicant on August 1, 2018. On October 4, 2018, FDA conducted a telecon to request the applicant provide clarifying information for the colorant ingredients in the new product packaging material for SE0014825. On October 10, 2018, FDA received an amendment containing the requested information (SE0014885).

Product Name	Original SE Report	Amendments
Copenhagen Long Cut Straight	SE0014825	SE0014885
Husky Long Cut Natural	SE0014826	None

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 August 1, 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 August 29, 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.

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), as required by section 905(j)(1)(A)(i) of the FD&C Act. The OCE review dated October 16, 2018 concludes 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 Karina Zuck on September 11, 2018.[1]

The chemistry review concludes that the new tobacco products have different characteristics related to product chemistry compared to the 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:

- In SE0014825, the new product includes a plastic can whereas the predicate product includes a fiberboard can with a Parafflex wax coating on the interior of the can.
- In SE0014626, the new product includes a metal lid and the predicate product includes a plastic lid.

In both SE Reports, the applicant included packaging information. However, it did not include sufficient detail on the colorant ingredient used in the new product packaging material. In the amendment submitted on October 10, 2018, the applicant provided the chemical composition of the colorant and a compliance statement from the vendor of the colorant. The ingredient differences identified in the packaging materials for SE0014825 and SE0014826 do not cause the new products to raise different questions of public health from a chemistry 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 from a chemistry perspective.

[1] An addendum, dated October 11, 2018, contains the chemistry review of the amendment (SE0014885) and concludes that the new tobacco products have different characteristics related to product chemistry compared to the predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health.

4.2. ENGINEERING

An engineering review was completed by Drew Katherine on September 10, 2018.

The 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

A microbiology review was completed by Wen Lin on September 13, 2018.

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:

- SE0014825
  - Change in container-closure system: plastic can with metal lid as opposed to fiberboard can with metal lid
  - Beginning of product storage: 98% increase in TAMC (on TSA SB)
  - End of product storage: 70% decrease in TAMC (on TSA SB)

- SE0014826
  - Change in container-closure system: plastic can with metal lid as opposed to plastic can with plastic lid
  - Beginning of product storage: 23% increase in TAMC (on TSA SB)
  - End of product storage: 20% increase in TAMC (on TSA SB)

The two new tobacco products have a change in the container closure system when compared to the corresponding predicate tobacco products. From a microbiology standpoint, change in final tobacco product packaging could potentially affect the moisture content and water activity (a_w) of the product. a_w is a measure of the amount of water that is available for microbial growth in a product. Therefore, changes to a_w could potentially affect microbial growth and product stability because microbial-mediated reactions play a key role in the accumulation of TSNAs in the final tobacco product during storage. For SE0014825, the TAMC (TSA SB) of the new product was higher (98%) than the predicate tobacco product at the beginning of product storage. However, this increase is not of concern because the TAMC (TSA SB) of the new tobacco product was lower (70%) than the predicate tobacco product at the end of product storage. Additionally, the new tobacco product also showed very minor changes in moisture content (≤4 %), a_w (≤1%), NNN (≤1%), NNK (≤5%) and total TSNA levels (≤2%) when compared to the predicate tobacco product at the beginning and end of product storage time. For SE0014826, the TAMC (TSA SB) of the new tobacco product was higher than the predicate tobacco product at the beginning (23%) and end (20%) of product storage. However, this increase is not of concern because the new tobacco product showed very minor

changes in moisture content (≤1 %), aw (≤1%), NNN (≤ 2), NNK (≤3%) and total TSNA levels (≤1%) when compared to the predicate tobacco product at the beginning and end of product storage time. Additionally, both new tobacco products have very low (≤ 5 cfu/g) TYMC over the complete storage time of the products. Microbial-mediated (b) (4) production is a key determinant of TSNA levels in the final tobacco product. The applicant provided data to show that the (b) (4) levels of the two new tobacco products were either below the method detection limit (b) (4) or the quantitation limit (b) (4) throughout the storage time of the 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 microbiology perspective.

4.4. TOXICOLOGY

A toxicology review was completed by Jueichuan Kang on September 7, 2018.

The toxicology review concludes that the new tobacco products have different characteristics related to product toxicology 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:

- A plastic can replace a fiberboard can (SE0014825)
- A metal lid replaces a plastic lid (SE0014826)

From a toxicology perspective, the new and corresponding predicate tobacco products have differences in packaging materials. Changes in packaging materials are not likely to raise additional toxicological concerns in the new tobacco products of SE0014825 and SE0014826 when compared with the corresponding predicate tobacco products. In addition, there are no significant changes in levels for various HPHCs (NNN, NNK, total TSNAs) between the new and 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 toxicology perspective.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Dilip Venugopal on September 4, 2018.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on October 22, 2018. The FONSI was supported by an environmental assessment prepared by FDA on October 22, 2018.

6. CONCLUSION AND RECOMMENDATION

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

- SE0014825
  - Replacement of a fiberboard can with a plastic can
  - 98% increase in TAMC at the beginning of product storage
  - 70% decrease in TAMC at the end of product storage
- SE0014826
  - Replacement of a plastic lid with a metal lid
  - 23% increase in TAMC at the beginning of product storage
  - 20% increase in TAMC at the end of product storage

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 indicated that the tobacco blend remained unchanged between the new and predicate tobacco products, and there are no differences in the ingredients other than tobacco in terms of quantity and quality. However, in both SE reports, the new and corresponding predicate tobacco products have different packaging materials. In SE0014825, the plastic can of the new product does not contain the enamel coating and Parafflex wax of the fiberboard can of the predicate product, thereby eliminating the potential of chemical leaching into the new tobacco product. Additionally, for SE0014825, a colorant is present in the plastic can; however, the chemistry and toxicology reviews conclude that this difference does not cause concerns. In SE0014826, an ingredient, (b) (4) is added to the new product packaging; however, the toxicology review concludes that this difference does not cause toxicological concerns. In both SE Reports, the applicant provided data demonstrating that there are no significant differences in the levels of HPHCs (NNN and NNK), (b) (4), and pH between the new and corresponding predicate tobacco products. The applicant also provided information on the stability of the new and predicate products by providing NNN, NNK, total TSNAs, pH, moisture, (b) (4), water activity (a_w), total aerobic microbial count (TAMC), and total mold and yeast counts (TYMC) over time. For SE0014525, the TAMC was higher at the beginning of the storage, and for SE0014526, the TAMC was higher at the beginning and end of product storage. However, these increases are not of concern because the new tobacco products showed very minor changes in moisture content, a_w, NNN, NNK, and total TSNA levels compared to the corresponding predicate products. Additionally, the TAMC of the new tobacco product of SE0014525 was lower than the predicate tobacco product at the end of product storage. This data demonstrates that the stability of the new tobacco products is not impacted by the changes in packaging materials. 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 tobacco 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.

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 SE0014825 and SE0014826, as identified on the cover page of this review.