FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0015107

SE0015107: Copenhagen Long Cut Straight	
Package Type	Fiberboard 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 Product
Product Sub-Category	Loose Moist Snuff
Recommendation	
Issue a Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Kenneth Taylor -S
Date: 2019.08.20 14:45:50 -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: 2019.08.20 14:51:35 -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 product:

SE0015107: 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

The predicate tobacco product is a loose moist snuff smokeless tobacco product manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 4, 2019, FDA received an SE Report (SE0015107) from Altria Client Services LLC (ALCS), on behalf of U.S. Smokeless Tobacco Company LLC (USSTC). FDA issued an Acknowledgement letter to the applicant on March 8, 2019. FDA issued an Advice/Information Request (A/I) letter to the applicant on April 30, 2019. On June 3, 2019, FDA received the applicant's response to the A/I letter (SE0015253).

Product Name	SE Report	Amendments
Copenhagen Long Cut Straight	SE0015107	SE0015253

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for this SE Report.

2. REGULATORY REVIEW

A regulatory review was completed by Pin Zhang on March 8, 2019.

The review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco product in SE0015107 was determined to be substantially equivalent by FDA under SE0014737. Therefore, the predicate tobacco product is an eligible predicate tobacco product.

The Office of Compliance and Enforcement (OCE) 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 review dated July 19, 2019, concludes that the new tobacco product is in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

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

4.1. CHEMISTRY

Chemistry reviews were completed by Youbang Liu on April 24, 2019 and on July 17, 2019.

The final chemistry review concludes that the new tobacco product has different characteristics related to product chemistry compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- Replacement of (b) (4) with an identical amount of (b) (4) (b) (4)
- Replacement of (b) (4) with an identical amount of (b) (4) (b) (4) in the (b)(4) tobacco component
- Addition of (b) (4) to the (b)(4) tobacco component
- Addition of (b) (4) to the (b)(4) tobacco component

Both (b) (4) are complex (b) (4) The (b) (4) contains one ingredient that is not present in the (b) (4) (b) (4) in the component) and does not contain 32 other ingredients that are present in the (b) (4) These ingredients comprise (b) (4) (b) (4) of this complex ingredient. Replacement of very small amount of (b) (4) (b) (4) with an identical amount of (b) (4) that contains fewer ingredients is not a concern. The amounts of (b) (4) tobacco and (b) (4) in the finished product is (b) (4) product and (b) (4) product, respectively. These ingredient changes are in amounts that are minor (≤0.01%), relative to the amount of the finished tobacco products, and do not cause concerns.

Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from a chemistry perspective.

4.2. ENGINEERING

An engineering review was completed by Gloria Kulesa on April 19, 2019.

The engineering review did not identify any differences in characteristics between the new and predicate tobacco products that could cause the new tobacco product to raise different questions of public health from an engineering perspective. Therefore, the differences in

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

4.3. MICROBIOLOGY

A microbiology review was completed by Wen S. Lin on April 19, 2019.

The microbiology review concludes that the new tobacco product has different characteristics related to product microbiology compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- Addition (b) (4)
- Addition (b) (4) tobacco
- Addition (b) (4)

The applicant provided a certification statement indicating that the new and predicate tobacco products differ in the additions of (b) (4) tobacco, (b) (4) (preservative) to the new tobacco product. The amounts of (b) (4) tobacco (b) (4) and (b) (4) added are not a concern because they are relatively small ingredient changes in the finished new tobacco product and are not anticipated to affect microbial activity. The amount of (b) (4) added to the new tobacco product is also minor (b) (4) and conventional microbial assays are not capable to assess the effect that this difference may have.

Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health related to product microbiology.

4.4. TOXICOLOGY

A toxicology review was completed by Prabha Kc on April 23, 2019.

The toxicology review concludes that the new tobacco product has different characteristics related to product toxicology compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- Addition of (b) (4) tobacco to the (b) (4) tobacco component
- Addition of (b) (4) to the (b)(4) tobacco component
- Substitution of (b) (4)

The (b) (4) tobacco replaces a similar amount of (b) (4) tobacco and would have potentially favorable effect in decreasing NNK and NNN levels. However, because the amount is so small, any effect on these HPHCs cannot be measured. Due to the relatively minor amount and tobacco type, this tobacco blend change is not anticipated to cause toxicological concerns. (b) (4) contains significantly fewer ingredients than (b) (4) and

some of those removed ingredients are of toxicological concern. Because the amount of the substituted ingredient is at sub-nanogram quantities and has fewer ingredients, this substitution is not a concern. The addition of (b) (4) is estimated to result in a daily exposure level of (b) (4) for adult consumers who use one can of the new product per day. This is significantly less than the US EPA's risk assessment for inorganic (b) (4) exposure, which has a calculated chronic population adjusted dose (cPAD) of 30 µg/kg/day. Accordingly, the addition of (b) (4) to the new tobacco product at the indicated levels is not anticipated to raise toxicological concerns.

Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from a toxicology perspective.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on July 16, 2019. The FONSI was supported by environmental assessments prepared by FDA on July 16, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Replacement of (b) (4) with (b) (4) (b) (4)
- Addition (b) (4) tobacco
- Addition (b) (4)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. There are no product design differences between the new and predicate tobacco products. The only differences in characteristics are the substitution of (b) (4) for (b) (4) and the addition of (b) (4) tobacco and (b) (4) to the (b) (4) tobacco component; all in very minor amounts. These ingredient changes won't cause measurable effects on harmful and potentially harmful constituents like NNK and NNN or other toxicants; or are 10^{-6} – fold less than calculated risk exposure amounts. Therefore, the differences in characteristics between the new and predicate products do not cause the new tobacco product to raise different questions of public health. Therefore, the differences in characteristics between the new and predicate products do not cause the new tobacco product to raise different questions of public health.

The predicate tobacco product was previously determined to be substantially equivalent by FDA under SE0014737.

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 SE0015107 was previously determined to be substantially equivalent by FDA under SE0014737. Comparison of the new tobacco product to the grandfathered product Copenhagen Long Cut Straight in SE0014737 reveals that the new tobacco product has the following differences in characteristics from Copenhagen Long Cut Straight, the grandfathered tobacco product:

- Substitution of (b) (4), with (b) (4) as an interior coating of the fiberboard can.
- Addition (b) (4)
- Addition (b) (4) tobacco
- Addition (b) (4) as a preservative

The differences in characteristics listed above, other than the differences in the substitution of (b) (4) (b) (4) and addition of (b) (4) tobacco and (b) (4) to the (b) (4) tobacco are the same differences in characteristics identified for the new and grandfathered tobacco products in (b) (4) Therefore, these differences do not cause the new tobacco product in SE0015107 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in the substitution of (b) (4), and addition of (b) (4) tobacco and (b) (4) to the (b) (4) tobacco between the new tobacco product in SE0015107 and the grandfathered tobacco product do not cause the new tobacco product to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0015107 to the predicate or grandfathered tobacco product, the new tobacco product does not raise different questions of public health.

The new tobacco product is currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude that the differences between the new and predicate tobacco products are such that the new tobacco product does not raise different questions of public health. I concur with these reviews and recommend that an SE order letter be issued.

FDA examined the environmental effects of finding the new tobacco product substantially equivalent and made a finding of no significant impact.

An SE order letter should be issued for the new tobacco product in SE0015107, as identified on the cover page of this review.