Technical Project Lead (TPL) Review: SE0015100 and SE0015103

SE0015100: Copenhagen Pouches	
Package Type	Plastic Can and Plastic Lid
Portion Count	15 Portions
Package Quantity	23.25 grams
Portion Mass	1550 mg/portion
Portion Length	40 mm
Portion Width	18 mm
Portion Thickness	5.51 mm[1]
Tobacco Cut Size	(b) (4)
Characterizing Flavor	None
Additional Property	Fine Cut
SE0015103: Copenhagen Pouches	
Package Type	Fiberboard Can with Metal Lid
Portion Count	15 Portions
Package Quantity	23.25 grams
Portion Mass	1550 mg/portion
Portion Length	40 mm
Portion Width	18 mm
Portion Thickness	5.51 mm[1]
Tobacco Cut Size	(b) (4)
Characterizing Flavor	None
Additional Property	Fine Cut
Common Attributes of SE Reports	
Applicant	U.S. Smokeless Tobacco Company LLC
Report Type	Regular
Product Category	Smokeless Tobacco Products
Product Sub-Category	Portioned Moist Snuff
Recommendation	
Issue Substantially Equivalent (SE) orders.	

[1] Calculated value

Technical Project Lead (TPL):

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Date: 2019.05.20 10:45:23 -04'00'

Jeannie Jeong-Im, 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: 2019.05.20 11:18:45 -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:

SE0015100: Copenhagen Pouches	
Product Name	PL Copenhagen Pouches
Package Type	Plastic Can and Plastic Lid
Portion Count	15 Portions
Package Quantity	23.25 grams
Portion Mass	1550 mg/portion
Portion Length	40 mm
Portion Width	18 mm
Portion Thickness	5.51 mm[1]
Tobacco Cut Size	(b) (4)
Characterizing Flavor	None
Additional Property	Fine Cut
SE0015103: Copenhagen Pouches	
Product Name	Copenhagen Pouches
Package Type	Fiberboard Can with Metal Lid
Portion Count	15 Portions
Package Quantity	23.25 grams
Portion Mass	1550 mg/portion
Portion Length	40 mm
Portion Width	18 mm
Portion Thickness	5.51 mm[1,2]
Tobacco Cut Size	(b) (4)
Characterizing Flavor	None
Additional Property	Fine Cut

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 1, 2019, FDA received two SE Reports from U.S. Smokeless Tobacco Company LLC. FDA issued Acknowledgement letters to the applicant on March 7, 2019. On April 1, 2019, FDA received an unsolicited amendment (SE0015156) from the applicant clarifying an inaccurate statement made about the grandfathered determination status for the predicate tobacco product subject of SE0015100.

[2] In the previously found SE product (SE0014616), the thickness was reported as a measured value of (b) (4) mm for the new tobacco product. However, it is reported in this SE Report as a calculated value and does not reflect a change in the product.

Product Name	SE Report	Amendments
Copenhagen Pouches	SE0015100	SE0015156
Copenhagen Pouches	SE0015103	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 Jessica Kiser on March 7, 2019.

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

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 SE0015100 is a grandfathered product (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated April 4, 2019, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and, therefore is an eligible predicate tobacco product.

The predicate tobacco product in SE0015103 was determined to be substantially equivalent by FDA under SE0014616. Therefore, this product is an eligible predicate tobacco product.

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) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated April 26, 2019, 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 Jason Hsieh on April 12, 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 in the tobacco:[3]

- Overall total amount of (b) (4) ((b) (4) mg/g tobacco) is replaced with ((b) (4) mg/g tobacco) of (b) (4) (GRAS):
  - Replacement of non-GRAS (b) (4) (b) (4) mg/g) in the (b) (4) with an identical amount of GRAS (b) (4)
  - Replacement of non-GRAS (b) (4) ((b) (4) mg/g) as a direct additive to the tobacco with an identical amount of GRAS (b) (4)
- Addition of (b) (4) mg/g of (b) (4) to the (b) (4)
- Addition of (b) (4) mg/g of (b) (4) tobacco to the (b) (4)
- <1% lower (b) (4), (b) (4), and (b) (4) tobaccos (b) (4) mg/g (b) (4), (b) (4) mg/g (b) (4), and (b) (4) mg/g (b) (4)) in the (b) (4)

The new and corresponding predicate tobacco products only differ slightly in (b) (4) (b) (4) t. The differences include adding (b) (4) mg/g of (b) (4) tobacco and (b) (4) mg/g of (b) (4) as a (b) (4) of the new tobacco products and replacing (b) (4) (non-GRAS) in the predicate tobacco products with (b) (4) (GRAS) in the corresponding new tobacco products. Also, there is a replacement of non-GRAS (b) (4) ((b) (4) mg/g) as a direct additive to the tobacco with an identical amount of GRAS (b) (4). The applicant provided a certified statement stating that, "...there are no other modifications to the materials, ingredients, design features, heating source, or any other feature of the New Product[s]." These minor differences between the new and corresponding predicate tobacco products are not expected to impact HPHC quantities, and therefore, they 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 April 10, 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:

- Addition ((b) (4) mg/g) of GRAS (b) (4) to replace identical amount of non-GRAS (b) (4) (b) (4)
- Addition ((b) (4) mg/g) of (b) (4) tobacco
- Addition ((b) (4) mg/g) of a preservative, (b) (4)

From a microbiology perspective, the small amounts of (b) (4) tobacco ((b) (4) mg/g) and GRAS (b) (4) ((b) (4) mg/g) added to the new tobacco products are not of concern. However, the addition of a preservative could potentially affect the microbial stability of the new tobacco products. The amount of (b) (4) added to the new tobacco products is small

[3] A chemistry memo dated May 17, 2019 corrected the amount of non-GRAS (b) (4) being replaced with GRAS (b) (4).

([redacted] mg/g) and conventional microbial assays are not sensitive enough to assess such small difference in the concentration of an analyte between the tobacco products. Therefore, from a microbiology perspective, the small amount ([redacted] mg/g) of [redacted] added to the new tobacco products does not cause the new tobacco products to raise different questions of public health.

5. ENVIRONMENTAL DECISION

An environmental science review was completed by William Brenner on April 11, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on May 7, 2019. The FONSI was supported by an environmental assessment prepared by FDA on May 7, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Replacement of non-GRAS [redacted] with an identical amount ([redacted] mg/g) of GRAS [redacted]
  - Replacement of non-GRAS [redacted] ([redacted] mg/g) in the [redacted] with an identical amount of [redacted]
  - Replacement of non-GRAS [redacted] ([redacted] mg/g) as a direct additive to the tobacco with an identical amount of GRAS [redacted]
- Addition of [redacted] mg/g of [redacted]
- Addition of [redacted] mg/g of [redacted] tobacco
- <1% lower [redacted], [redacted], and [redacted] tobaccos [redacted] mg/g [redacted], [redacted] mg/g [redacted] and [redacted] mg/g [redacted]

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The amount of [redacted] tobacco added, [redacted], [redacted] and [redacted] tobaccos displaced, and [redacted] added to the [redacted] of the new products are minor and not expected to lead to detectable increases in HPHCs. Since the [redacted] is going from non-GRAS to GRAS, the toxicity of the new products is expected to be no worse than the corresponding predicate products. 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 for SE0015100 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 product for SE0015103 was previously determined to be substantially equivalent by FDA under SE0014616. 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). Comparison of the new tobacco product to the grandfathered products (Copenhagen Pouches in SE0014616) reveals that the new tobacco product has the following differences in characteristics from the grandfathered tobacco product:

- Replacement of (b) (4) with (b) (4) coating on the inside of the fiberboard can
- Replacement of non-GRAS (b) (4) ((b) (4) mg/g) with an identical amount of GRAS (b) (4)
    - Replacement of non-GRAS (b) (4) ((b) (4) mg/g) in the (b) (4) with an identical amount of GRAS (b) (4)
    - Replacement of non-GRAS (b) (4) ((b) (4) mg/g) as a direct additive to the tobacco with an identical amount of GRAS (b) (4)
- Addition of (b) (4) mg/g of (b) (4) in (b) (4)
- Addition of (b) (4) mg/g of (b) (4) tobacco in (b) (4)
- <1% lower (b) (4), (b) (4), and (b) (4) tobaccos (b) (4) mg/g (b) (4), (b) (4) mg/g (b) (4) and (b) (4) mg/g (b) (4)

The differences in characteristics listed above, other than the differences in (b) (4) and (b) (4), are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0014616. Therefore, these differences do not cause the new tobacco product in SE0015103 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in (b) (4) coating on the inside of the fiberboard can and changes in the (b) (4) between the new tobacco product in SE0015103 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 SE0015103 to the predicate or grandfathered tobacco products, the new tobacco product does not 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 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 SE0015100 and SE0015103, as identified on the cover page of this review.