FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0015624

SE0015624: Copenhagen Long Cut Select	
Package Type	Fiberboard Can/Metal Lid
Package Quantity	34.02 grams (g)
Tobacco Cut Size	(b)(4) Cuts Per Inch (CPI)
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: 2020.03.18 15:13:00 -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: 2020.03.18 15:19:27 -04'00'

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0015624: Copenhagen Long Cut Select	
Product Name	Copenhagen Long Cut
Package Type	Fiberboard Can/Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b)(4) CPI
Characterizing Flavor	None

The predicate tobacco product (GF1200190) is a loose moist snuff smokeless tobacco product manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On December 20, 2019, FDA received one SE Report from Altria Client Services LLC, on behalf of U.S. Smokeless Tobacco Company LLC. On December 27, 2019, FDA issued an Acceptance letter to the applicant.

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 Samuel Motto on December 27, 2019.

The review concludes that the SE Report is 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 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 January 22, 2020, 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.

OCE also completed a review to determine whether the new tobacco product is 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 February 12, 2020, 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

A chemistry review was completed by Youbang Liu on February 10, 2020.

The 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:

- (b) (4) Tobacco
- 19% analytically significant increase in (b) (4)
- 21% analytically significant increase in (b) (4)
- 31% analytically significant increase in (b) (4)

The new tobacco product uses (b) (4) in the same quantities as conventiona (b) (4) contained in the predicate tobacco product. (b) (4) (b)(4) . There is a 53% decrease in N-Nitrosonornicotine (NNN) in the new tobacco product compared to the predicate tobacco product, which demonstrates that the use of (b) (4) in the tobacco blend is not a concern. The analytically significant increases in (b) (4) are deferred to toxicology.

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 Raymond L. Williamson on February 04, 2020.

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.

[1] (b)(4)

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

4.3. MICROBIOLOGY

A microbiology review was completed by Wen S. Lin on February 10, 2020.

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:

- Use of (b) (4) [redacted]
- 29 - 59% decreases in TAMC[2] during product storage
- Decreases in NNN (53 - 55%), NNK[3] (42-46%) and total TSNAs (42 - 44%) during product storage

The decreases in NNN, NNK, total TSNAs and TAMC during storage times demonstrate that the new tobacco product is more stable than the predicate tobacco product.

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 microbiology perspective.

4.4. TOXICOLOGY

A toxicology review was completed by Vyomesh Patel on February 24, 2020.

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

- Use of (b) (4) [redacted]
- Analytically significant increases in (b) (4) [redacted]

The use of (b) (4) [redacted] in the new tobacco product does not cause toxicology concerns due to the significant decreases in both NNN and NNK. Additionally, the decreases in NNN and NNK appear to offset the cancer risks from the increases in (b) (4) [redacted]

(b) (4) [redacted]

Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco products 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 February 26, 2020. The FONSI was supported by an environmental assessment prepared by FDA on February 26, 2020.

6. CONCLUSION AND RECOMMENDATION

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

- (b) (4) (b)(4) Tobacco
- 19% analytically significant increase in (b) (4)
- 21% analytically significant increase in (b) (4)
- 31% analytically significant increase in (b) (4)
- 29 - 59% decreases in TAMC during product storage
- Decreases in NNN (53 - 55%), NNK (42-46%) and total TSNAs (42 - 44%) during product storage

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. The new tobacco product has analytically significant decreases in NNN and NNK, which offset the analytically significant increases in (b) (4) given that NNN and NNK are more potent carcinogens. Additionally, NNN, NNK, total TSNAs, and TAMC decreased during storage of the new tobacco product, indicating that it has better stability. As a result, the change in tobacco blend, namely, using (b) (4) in place of the conventional tobacco types is not a concern. 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 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 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 SE0015624, as identified on the cover page of this review.