FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review:

SE0014494 - SE0014498

SE0014494: Copenhagen Pouches	
Package Type	Fiberboard Can and Metal Lid
Package Quantity	23.25 g
Portion Count	15 portions
Portion Mass	1550 mg/portion
Portion Length	40 mm
Portion Width	18 mm
Portion Thickness	4.88 mm
Tobacco Cut Size	(b [redacted] Cuts per Inch (CPI)
Characterizing Flavor	None
Additional Property	Fine Cut
SE0014495: Copenhagen Snuff Fine Cut	
Package Type	Fiberboard Can and Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b [redacted] CPI
Characterizing Flavor	None
SE0014496: Copenhagen Long Cut Black	
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b) [redacted] CPI
Characterizing Flavor	Whiskey
SE0014497: Copenhagen Long Cut Straight	
Package Type	Fiberboard Can and Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b) [redacted] CPI
Characterizing Flavor	None
SE0014498: Copenhagen Long Cut	
Package Type	Fiberboard Can and Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b) [redacted] CPI
Characterizing Flavor	None

Common Attributes of SE Reports	
Applicant	U.S. Smokeless Tobacco Company
Report Type	Regular
Product Category	Smokeless Tobacco Product
Product Sub-Category	Portioned Moist Snuff (SE0014494) Loose Moist Snuff (SE0014495 – SE0014498)
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Matthew J. Walters, Ph.D., M.P.H.
CDR, US Public Health Service
Deputy 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)

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0014494: Copenhagen Pouches	
Product Name	Copenhagen Pouches
Package Type	Fiberboard Can and Metal Lid
Package Quantity	23.25 g
Portion Count	15 portions
Portion Mass	1550 mg/portion
Portion Length	40 mm
Portion Width	18 mm
Portion Thickness	4.88 mm
Tobacco Cut Size	(b) CPI
Characterizing Flavor	None
Additional Property	Fine Cut
SE0014495: Copenhagen Snuff Fine Cut	
Product Name	Copenhagen Snuff Fine Cut
Package Type	Fiberboard Can and Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b CPI
Characterizing Flavor	None
SE0014496: Copenhagen Long Cut Black	
Product Name	Copenhagen Long Cut Black
Package Type	Plastic Can with Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b) CPI
Characterizing Flavor	Whiskey
SE0014497: Copenhagen Long Cut Straight	
Product Name	Copenhagen Long Cut Straight
Package Type	Fiberboard Can and Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b CPI
Characterizing Flavor	None
SE0014498: Copenhagen Long Cut	
Product Name	Copenhagen Long Cut

Package Type	Fiberboard Can and Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	(b CPI
Characterizing Flavor	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On February 1, 2018, FDA received five SE Reports (SE0014494 - SE0014498) from U.S. Smokeless Tobacco Company. FDA issued an Acknowledgement letters to the applicant on February 8, 2018. FDA issued an Advice/Information Request (A/I) letter on April 26, 2018. On June 14, 2018, FDA received the response (SE0014767) to the A/I letter.

Product Name	SE Report	Amendments
Copenhagen Pouches	SE0014494	SE0014767
Copenhagen Snuff Fine Cut	SE0014495	
Copenhagen Long Cut Black	SE0014496	
Copenhagen Long Cut Straight	SE0014497	
Copenhagen Long Cut	SE0014498	

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 Sarah Webster on February 8, 2018,[1] and on April 25, 2018.[2]

The 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 March 9, 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.

[1] For SE0014494 - SE0014498
[2] For SE0014494 only

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 July 24, 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 discipline:

4.1. CHEMISTRY

A Chemistry review was completed by Melis Coraggio on March 29, 2018[3].

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 difference:

- (b) (4)(b) (4) (non-GRAS) replaced with equal amount of (b) (4) (GRAS[4])

These SE Reports included minimal information about the tobacco blend and ingredients other than tobacco for the new and predicate products. However, the applicant provided ingredients other than tobacco for the new and predicate products along with a certification statement signed by a responsible official authorized to act on behalf of the company (USSTC) stating that "the characteristics of the new and predicate product are identical in all aspects with the exception… replacement of non-GRAS (b) (4) (b) (4) in the predicate product with an identical amount of GRAS (b) (4) in the new product...." The only modification between the new and corresponding predicate products is the change in the flavor ingredient, non-GRAS (b) (4), (b) (4) to a GRAS (b) (4) with the exact same quantity (0.0001 mg/gram). Therefore, the difference in characteristics between the new and corresponding predicate tobacco products does not cause the new tobacco product to raise different questions of public health related to product chemistry.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Thomas Creaven on April 4, 2018.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on September 5, 2018. The FONSI was supported by an environmental assessment prepared by FDA on September 5, 2018.

[3] A memo was written on June 6, 2018 to clarify a discrepancy in the 1st chemistry review regarding the subcategories for the predicate tobacco products. This memo does not change the conclusions of the 1st chemistry review dated March 29, 2018.
[4] GRAS: Generally Recognized as Safe

6. CONCLUSION AND RECOMMENDATION

The following is the only difference in characteristics between the new and corresponding predicate tobacco products:

- (b) (4) , (b) (4) (non-GRAS) replaced with equal amount of (b) (4) (GRAS)

The applicant has demonstrated that this difference in characteristics does not cause the new tobacco products to raise different questions of public health. These SE Reports included minimal information about the tobacco blend and ingredients other than tobacco for the new and predicate products. However, the applicant provided ingredients other than tobacco for the new and predicate products along with a certification statement signed by a responsible official authorized to act on behalf of the company (USSTC) stating that "the characteristics of the new and predicate product are identical in all aspects with the exception… replacement of non-GRAS (b) (4) , (b) (4) in the predicate product with an identical amount of GRAS (b) (4) in the new product...." The only modification between the new and corresponding predicate products is the change in the flavor ingredient, non-GRAS (b) (4) , (b) (4) to a GRAS (b) (4) with the exact same quantity (0.0001 mg/gram). Therefore, the difference in characteristics between the new and corresponding predicate products does 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 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, the chemistry review concludes that the difference between the new and corresponding predicate tobacco products is such that the new tobacco products do not raise different questions of public health. I concur with this review 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 SE0014494 – SE0014498, as identified on the cover page of this review.