FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review:

SE0014737 and SE0014738

SE0014737: Copenhagen Long Cut Straight	
Package Type	Fiberboard Can and Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	[redacted] CPI
Characterizing Flavor	None
SE0014738: Copenhagen Snuff Fine Cut	
Package Type	Fiberboard Can and Metal Lid
Package Quantity	34.02 g
Tobacco Cut Size	[redacted] CPI
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	US Smokeless Tobacco Company LLC
Report Type	Regular
Product Category	Smokeless Tobacco Product
Product Sub-Category	Loose Moist Snuff
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Matthew J. Walters -S
2018.08.15 10:28:55 -04'00'

Matthew J. Walters, Ph.D., M.P.H.
CDR, U.S. 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)

Digitally signed by Matthew R. Holman -S
Date: 2018.08.15 10:35:45 -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:

SE0014737: 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	[redacted] CPI
Characterizing Flavor	None
SE0014738: 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	[redacted] CPI
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 May 31, 2018, FDA received two SE Reports from Altria Client Services (LLC) on behalf of US Smokeless Tobacco Company LLC. FDA issued Acknowledgement letters to the applicant on June 4, 2018. On July 11, 2018, FDA conducted a teleconference to request the applicant provide clarifying information regarding laboratory accreditation for SE0014737 and SE0014738 and nitrite quantities for SE0014737. On July 18, 2018, FDA received a solicited amendment (SE0014821) containing the requested information.

Product Name	SE Report	Amendments
Copenhagen Long Cut Straight	SE0014737	SE0014821
Copenhagen Snuff Fine Cut	SE0014738	

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 June 4, 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 June 27, 2018 and June 28, 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) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated August 13, 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 Megan Mekoli on July 24, 2018.

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:

- Addition of wax coating on the fiberboard as (b) (4)(b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)
- Deletion of wax coating on the fiberboard as (b) (4)(b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4)

The only notable difference between the new and corresponding predicate products was the wax coating on the fiberboard can. Both wax coatings are generally regarded as safe (GRAS) for contact with food and, therefore, do not cause the new products to raise different questions of public health with regards to chemistry. Otherwise, the new products are identical to the corresponding predicate products. In addition, the new product HPHC quantities were not statistically different from those of the corresponding predicate 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 chemistry perspective.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Thomas Creaven on July 13, 2018.

The final environmental review found that the SE Reports do not provide enough information for an Environmental Assessment for the new products as required in 21 CFR 25.40. Specifically, the environmental review found:

- The applicant did not specify the marketing intentions for the predicate products after receiving marketing orders for the new products.

Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI).

6. CONCLUSION AND RECOMMENDATION

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

- Addition of wax coating on the fiberboard can as (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4)(b) (4)(b) (4)
- Deletion of wax coating on the fiberboard as (b) (4)(b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. Both wax coatings are generally regarded as safe (GRAS) for contact with food and, therefore, do not cause the new products to raise different questions of public health with regards to chemistry. Otherwise, the new products are identical to the corresponding predicate products. In addition, the new product HPHC quantities were not statistically different from those of 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 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 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 this review and recommend that SE order letters be issued.

FDA examined the environmental effects of finding these new tobacco products substantially equivalent and found additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing an SE order.

An Advice/Information Request letter should be issued requesting the following information:

1. Both of your SE Reports lack information regarding the marketing intentions for the predicate products after receiving marketing orders for the new products. Marketing information is used to quantitatively assess the environmental impacts of manufacturing,

use and disposal of the predicate products. Address the following issues concerning marketing of the predicate products:

a. State if the predicate products will be marketed after the new products receive marketing orders.
b. Provide the first-year and fifth- year market projections for the predicate products, if the intent is to market the predicate products simultaneously with the new products.
c. Describe how manufacturing the predicate products will impact the emissions of the Nashville manufacturing facility, if the intent is to market the predicate products simultaneously with the new products.

If the applicant adequately responds to the request and an EIS or FONSI is completed, SE order letters should be issued for the new tobacco products in SE0014737 and SE0014738, as identified on the cover page of this review.