FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0014449 and SE0014450

SE0014449: Hot Rod Smooth King Size 100 Count	
Package Type	Box
Package Quantity	100 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	None[1]
SE0014450: Hot Rod Menthol King Size 100 Count	
Package Type	Box
Package Quantity	100 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	Menthol[1]
Common Attributes of SE Reports	
Applicant	Midwest Tobacco Tube Inc. dba Great Midwest Tube
Report Type	Regular Product Quantity Change
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Filtered Cigarette Tube
Recommendation	
Issue Substantially Equivalent (SE) orders.	

[1] As provided by the applicant's certification statement. For product quantity change SE Reports, FDA does not conduct substantive scientific review to evaluate the information contained in the applicant's certification statement.

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2018.06.25 14:27:31 -04'00'

Colleen K. Rogers, Ph.D.
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 Glen D. Jones -S
Date: 2018.06.26 10:40:15 -04'00'

For 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:

SE0001498: Hot Rod Smooth King Size 200 Count	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	None[1]
SE0001500: Hot Rod Menthol King Size 200 Count	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	Menthol[1]

The predicate tobacco products are roll-your-own cigarette tubes manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On December 21, 2017, FDA received two product quantity change substantial equivalence reports (SE Reports) for the tobacco products listed above from Midwest Tobacco Tube Inc. dba Great Midwest Tube. FDA issued an Acknowledgement letter on December 28, 2017. On March 20, 2018, FDA issued an Advice/Information request (A/I) letter requesting environmental information. On March 28, 2018, FDA received the applicant's amendment (SE0014956) responding to FDA's A/I letter. On March 30, 2018, FDA requested additional environmental information. On April 2, 2018, FDA received the applicant's amendment (SE0014603) responding to FDA's additional environmental information request.

Product Name	SE Report	Amendments
Hot Rod Smooth King Size 100 Count	SE0014449	SE0014596
Hot Rod Menthol King Size 100 Count	SE0014450	SE0014603

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 Brandon Rose on December 21, 2017 and June 7, 2018.

The reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco products in SE0014449 and SE0014450 were determined to be substantially equivalent by FDA under SE0001498 and SE0001500, respectively[2]. Therefore, the predicate tobacco products are eligible predicate tobacco products.

The Office of Compliance and Enforcement (OCE) 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 June 6, 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. SOCIAL SCIENCE

A social science review was completed by David Portnoy on March 13, 2018.

The social science review concludes that the new tobacco products have different characteristics from the corresponding predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health from a social science perspective. While not specifically stated in the social science review, I note the following difference:

- 50% decrease in product quantity (from 200 to 100 tubes)

The social science review concludes that the differences in product quantity do not cause the new tobacco products to raise different questions of public health, citing a memorandum[3] prepared by the Office of Science (OS). That memorandum summarizes OS's current thinking on product quantity changes, which supports OS' determination that, at this time, changes in tobacco product quantity do not cause new tobacco products to raise different questions of

[2] These SE Reports (SE0001498 and SE0001500) were submitted as Same Characteristics SE Reports (i.e., the applicant asserted that the new tobacco products had identical characteristics to but a different label from the corresponding predicate tobacco products), and the new tobacco products were found substantially equivalent to the corresponding grandfathered, predicate tobacco products on May 19, 2016. Consistent with a decision of the U.S. District Court for the District of Columbia (see *Philip Morris USA Inc. v. United States Food and Drug Administration*, 202 F. Supp. 3d 31 (D.D.C. 2016)), a modification to an existing tobacco product's label, standing alone, does not result in a new tobacco product subject to the premarket review provisions of the FD&C Act. Since the new tobacco products in SE0001498 and SE0001500 are identical to the corresponding grandfathered, predicate tobacco products identified in those SE Reports, the new tobacco products in SE0001498 and SE0001500 are themselves grandfathered tobacco products.

[3] *See* memorandum on product quantity changes, dated December 7, 2017.

public health. Consequently, the change in product quantity does not cause the new tobacco products to raise different questions of public health from a social science perspective.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Shannon Hanna on March 6, 2018.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on June 22, 2018. The FONSI was supported by an environmental assessment prepared by FDA on June 22, 2018.

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate tobacco products are identical except for the following changes in product quantity:

- SE0014449 and SE0014450: 50% decrease in product quantity

The social science review and OS memorandum[4] conclude that based on OS' experience and the currently available evidence, the difference in product quantity does not cause the new tobacco products to raise different questions of public health. I concur with this conclusion.

The predicate tobacco products in SE0014449 and SE0014450 were previously determined to be substantially equivalent by FDA under SE0001498 and SE0001500, respectively. Additionally, as explained above, the predicate tobacco products in SE0014449 and SE0014450 meet statutory requirements because it was determined that they are grandfathered tobacco 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.

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 SE0014449 and SE0014450, as identified on the cover page of this review.

[4] *See* memorandum on product quantity changes, dated December 7, 2017.