FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0014064

SE0014064: High Card Gold 100MM	
Package Type	Box
Package Quantity	250 tubes
Length	100 mm
Diameter	8.11 mm
Ventilation	(b) (4)
Characterizing Flavor[1]	None
Attributes	
Applicant	Republic Tobacco, LP
Report Type	Regular Product Quantity Change
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Filtered Cigarette Tube
Recommendation	
Issue a Substantially Equivalent (SE) order.	

[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: 2017.09.21 13:13:11 -04'00'

Colleen K. Rogers, Ph.D.
Director
Division of Product Science
Office of 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: 2017.09.22 13:28:06 -04'00'

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant certifies that the predicate tobacco product is identical to the new tobacco product except for product quantity. According to the applicant, the predicate tobacco product has the following characteristics:

SE0003199: Top Gold 100MM	
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.11 mm
Ventilation	(b)(4)
Characterizing Flavor	None

The predicate tobacco product is manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On April 21, 2017, FDA received a Product Quantity Change SE Report from Republic Tobacco, LP. FDA issued an Acknowledgment letter to the applicant on April 28, 2017. After an environmental review was conducted on June 16, 2017, FDA issued a Preliminary Finding letter on June 22, 2017. The Preliminary Finding letter identified environmental deficiencies in the applicant's SE Report. The applicant submitted a response (SE0014190) on July 3, 2017.

Product Name	SE Report	Amendment
High Card Gold 100MM	SE0014064	SE0014190

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for this SE Report.

2. REGULATORY REVIEW

Regulatory reviews were completed by Sarah Webster on April 28, 2017, and September 18, 2017.

The final review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco product in SE0014064 was previously found to be substantially equivalent by FDA under SE0003199. Therefore, the predicate tobacco product is an eligible predicate tobacco product.

The Office of Compliance and Enforcement (OCE) 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 August 31, 2017, 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 discipline:

4.1. SOCIAL SCIENCE

A social science review was completed by Rhonda Moore on June 14, 2017.

The social science review concludes that the new tobacco product has different characteristics compared to the predicate tobacco product but that the differences do not cause the new tobacco product to raise different questions of public health from a social science perspective. The review identified the following difference between the new and predicate tobacco products: an increase in product quantity from 200 tubes to 250 tubes (+25%). The social science reviewer states that there is currently no available scientific evidence that this minor change in the number of tubes per box influences consumer perceptions of harm or use intentions. Further, the reviewer states that evidence from other consumer products suggests that this change in the number of tubes per box would not cause the new tobacco product to raise different questions of public health from a social science perspective.

As explained in FDA's Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (3d Edition), increasing product quantity can potentially reduce cessation behaviors and increase tobacco product use among current users. However, when that evidence is viewed in the context of the evidence provided in this SE Report, as well as other scientific literature and FDA's general experience reviewing SE Reports, based on the current state of the evidence, for the class of products at issue here—cigarette tubes—an increase in product quantity would not cause a new tobacco product to raise different questions of public health. As described in the social science review, for consumer products that are "usage-invariant" (i.e., products which have price insensitive demand functions), increasing the product quantity generally would not impact consumer use. Relatedly, scientific literature suggests that for consumer products that are "low convenience" (i.e., products that require preparation and for which consumption costs time, comfort, and effort) and "low salience" (i.e., products that are not noticeable, easily remembered, or recalled), increasing the product quantity also generally would not impact consumer use.[2] Given the likelihood that cigarette tubes are usage-invariant (since there is no benefit of using an increased number of cigarette tubes per quantity of RYO tobacco), low convenience (since they must be used with other products and require additional preparation before consumption), and low salience (since they are not highly visible, requiring little storage space), I find that, based on the current state of the evidence, an increase of product quantity from 200 to 250 tubes does not cause the new tobacco product to raise different questions of public health.

[2] Chandon, P. & Wansink, B. (2002). When are stockpiled products consumed faster? A convenience-salience framework of postpurchase consumption incidence and quantity. Journal of Marketing Research, 321-335.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on September 13, 2017. The FONSI was supported by an environmental assessment prepared by FDA on September 13, 2017.

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and predicate tobacco products are identical except for a change in product quantity from 200 to 250 RYO filtered cigarette tubes.

The social science review concludes that this difference in product quantity does not cause the new tobacco product to raise different questions of public health. I concur with the conclusion of the social science review.

The predicate tobacco product meets statutory requirements because it was determined to be substantially equivalent by FDA under SE0003199.

The new tobacco product is currently in compliance with the FD&C Act.

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 SE0014064 as identified on the cover page of this review.