Technical Project Lead (TPL) Review: SE0013713 and SE0013715

SE0013713: GAMBLER SINGLE WIDE	
Package Type	Booklet
Package Quantity	24 papers
Length	70 mm
Width	39 mm
Characterizing Flavor[1]	None
SE0013715: GAMBLER SINGLE WIDE	
Package Type	Booklet
Package Quantity	50 papers
Length	70 mm
Width	39 mm
Characterizing Flavor[1]	None
Common Attributes of SE Reports	
Applicant	Republic Tobacco, LP
Report Type	Regular
Product Category	Roll-Your-Own tobacco product
Product Sub-Category	Rolling papers
Recommendation	
Issue Substantially Equivalent (SE) orders.	

[1] As provided by applicant's certification statement. FDA does not conduct substantive scientific review to determine whether the characteristics are the same for Product Quantity Change SE Reports.

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2017.06.07 10:55:37 -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 Matthew R. Holman -S
Date: 2017.06.07 12:50:09 -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 (same for both SE0013713 and SE0013715) has identical properties to the new tobacco products except for product quantity. The predicate tobacco product has the following characteristics:

SE0013713 and SE0013715: Top Cig Paper 24's[2]	
Package Quantity	100 papers
Length	70 mm
Width	39 mm
Characterizing Flavor[1]	None

The predicate tobacco product is manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On September 28, 2016, FDA received Product Quantity Change SE Reports from Republic Tobacco, LP. FDA issued Acknowledgment letters to the applicant on October 5, 2016. After a first round of scientific review, FDA issued a Preliminary Finding letter on December 22, 2016. The applicant responded with amendment SE0013820. In response to the Office of Compliance and Enforcement's information request, the applicant responded with amendment SE0014095.

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 October 5, 2016 and May 26, 2017.

The final review concludes that the SE Reports are administratively complete.

[2] In the original application the applicant referenced the predicate product as Top Standard. However, the applicant also included an explanatory note under section 3, "Status of predicate product", that on February 15, 2007, the predicate product name was Top Cig Paper 24's. The predicate eligibility determination review was conducted under the predicate product name Top Cig Paper 24's.

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 as of February 15, 2007). The OCE review dated November 1, 2016, and the addendum dated May 24, 2017, conclude 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 products are 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 April 25, 2017, concludes that the new tobacco products are 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 Shari Feirman on November 21, 2016.

The social science review concludes that the new tobacco products have different characteristics related to consumer perception compared to the predicate tobacco product but the differences do not cause the new tobacco products to raise different questions of public health. The new and predicate tobacco products have the following differences in package quantity:

- SE0013713: Decrease of 76% (100 to 24 papers)
- SE0013715: Decrease of 50% (100 to 50 papers)

The review states that evidence from studies of usage-invariant and low convenience consumer products suggests that these differences in package quantity would not cause the new tobacco products to raise different questions of public health. Therefore, the differences in product characteristics related to consumer perception (e.g. differences in product quantity) and use between the new and predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

The applicant provided both a health information summary and a statement. The health information summary does not contain any language that would potentially violate section 911 of the FD&C Act.[3]

[3] Due to the inclusion of the health information statement, the order letter will reflect the potential options for how to satisfy a health information summary when the applicant is “requested by any person”.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on March 14, 2017. The FONSI was supported by an environmental assessment prepared by FDA on March 13, 2017.

6. CONCLUSION AND RECOMMENDATION

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

- SE0013713: Decrease of 76% (100 to 24 papers)
- SE0013715: Decrease of 50% (100 to 50 papers)

The social science review concludes that these differences between the new and predicate tobacco products do not cause the new tobacco products to raise different questions of public health. I concur with the social science review.

The predicate tobacco products meet statutory requirements because they are grandfathered products (i.e., were commercially marketed in the United States 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 SE0013713 and SE0013715 as identified on the cover page of this review.