

Technical Project Lead (TPL) Review:

SE0014705, SE0014706, and SE0014707

SE0014705: Republic El Rey Regular 100MM	
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.2 mm
Ventilation	None
Characterizing Flavor	None
SE0014706: Republic El Rey Menthol King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.2 mm
Ventilation	None
Characterizing Flavor	Menthol
SE0014707: Republic El Rey Regular King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.2 mm
Ventilation	None
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Republic Tobacco, LP
Report Type	Regular
Product Category	Roll-Your-Own Tobacco Product
Product Sub-Category	Filtered Cigarette Tubes
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Matthew J. Walters -S
2018.07.31 11:36:03 -04'00'

For Kenneth M. Taylor, Ph.D.
Chemistry Branch Chief
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: 2018.07.31 13:41:55 -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:

SE0014705: Republic El Rey Regular 100MM	
Product Name	Top Regular 100MM
Package Type	Box
Portion Count	200 tubes
Length	100 mm
Diameter	8.2 mm
Ventilation	None
Characterizing Flavor	None
SE0014706: Republic El Rey Menthol King Size	
Product Name	Top Menthol King Size
Package Type	Box
Portion Count	200 tubes
Length	84 mm
Diameter	8.2 mm
Ventilation	None
Characterizing Flavor	Menthol
SE0014707: Republic El Rey Regular King Size	
Product Name	200CT GAMBLER REG TUBE
Package Type	Box
Portion Count	200 tubes
Length	84 mm
Diameter	8.2 mm
Ventilation	None
Characterizing Flavor	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On May 3, 2018, FDA received three SE Reports (SE0014705, SE0014706, and SE0014707) from Republic Tobacco, LP. FDA issued Acknowledgement letters to the applicant on May 8, 2018.

Product Name	SE Report	Amendments
Republic El Rey Regular 100MM	SE0014705	None
Republic El Rey Menthol King Size	SE0014706	
Republic El Rey Regular King Size	SE0014707	

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 Nicholas Hasbrouck on May 8, 2018.

The final reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the predicate tobacco product in SE0014707 is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated June 07, 2018, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product in SE0014707 is grandfathered and, therefore is an eligible predicate tobacco product.

The predicate tobacco products in SE0014705 and SE0014706 were determined to be substantially equivalent by FDA under SE0003200 and SE0012366 respectively. Therefore, the predicate tobacco products in SE0014705 and SE0014706 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 July 31, 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 Selvin Edwards on June 18, 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:

SE0014705:

- Glue Seam/Filter – 184% higher (b)(4)
- Plug Wrap – 8% higher (b)(4)
- Acetate Tow – 11% higher (b)(4), 11% higher (b)(4), 10% higher (b)(4)
- Tipping Glue – 100% higher (b)(4)

SE0014706:

- Tipping Paper – 6% higher (b)(4), 100% higher (b)(4), 100% (b)(4), 990% (b)(4)
- Glue Seam/Filter – 222% higher (b)(4)
- Plug Wrap – 10 % higher (b)(4)
- Tipping Glue – 100% higher (b)(4)

SE0014707:

- Glue Seam/Filter – 180% higher (b)(4), 12% higher (b)(4)
- Tipping Glue – 16% higher (b)(4)
- Plug Wrap – 100% higher (b)(4)

For many of these ingredient increases, the ingredient quantities are less than 0.1% of the product and are located in the non-combusted components of the cigarette tubes. Therefore, these ingredient changes are not expected to affect smoke chemistry. TNCO smoke yields under ISO smoking regimen are lower for the new tobacco products compared to the corresponding predicate tobacco products with the exception of SE0014706. For SE0014706, the new tobacco product has a 9% higher nicotine yield, but the absolute difference in nicotine yield is only 0.087 mg-per-tube, which does not raise concerns. 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.

4.2. ENGINEERING

An engineering review was completed by James Cheng on June 28, 2018.

The engineering review concludes that the new tobacco products have different characteristics related to product engineering 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:

- Decreases in tipping paper length (↓3.6%-4%)
- Decreases in tube mass (↓0.4%-6.6%)
- Differences in filter density (↓6.1% - ↑7.3%)
- Differences in total denier (↓11% - ↑11%)
- Differences in denier per filament (↓5.3 – 14%) for SE0014706 and SE0014707
- Increases in pressure drop (↑5.6-14%) for SE0014705 and SE0014707

Differences in tipping paper length do not typically affect smoke constituents as tipping paper is not combusted. Reductions in tube mass may reduce smoke constituent yields as there is less material to be combusted. Differences in filter density, filter tow and filter pressure drop may affect filter efficiency and smoke constituent yields. The applicant provided TNCO testing under ISO testing parameters that show that the new products have reduced or comparable TNCO yields compared to the corresponding predicate products as explained by the chemistry review. 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 an engineering perspective.

4.3. TOXICOLOGY

A toxicology review was completed by Ines Pagan on June 26, 2018.

The toxicology review concludes that the new tobacco products have different characteristics related to product toxicology 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 or increase of (b) (4) paper to the plug wrap in SE0014705 and SE0014706
- Increase in (b) (4) in the tipping paper in SE0014706.
- Addition of (b) (4) to the filter glue seam adhesive in SE0014707
- Increase in (b) (4) in SE0014707

These ingredient changes are in the non-combusted filter component. As a result, in this case, the filter components are not expected to volatilize directly or thermally degrade into HPHCs to the mainstream smoke or be released from the filter. 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 toxicology perspective.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on July 20, 2018. The FONSI was supported by an environmental assessment prepared by FDA on July 20, 2018.

6. CONCLUSION AND RECOMMENDATION

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

- Ingredient additions or increases to various filter components
 - Filter glue seam adhesive, filter plug wrap, tipping paper glue in the new tobacco products (all SE Reports)
 - Acetate tow (SE0014705)

- Tipping paper (SE0014706)
- (b) (4) (SE0014707)
- Decreases in tipping paper length (↓ 3.6 – 4%)
- Decreases in tube mass (↓ 0.4% – 6.6%)
- Differences in filter density (↓ 6.1% – ↑ 7.3%)
- Differences in total denier (↓ 11% – ↑ 11%)
- Decreases in denier per filament (↓ 5.3 – 14%) (SE0014706 and SE0014707)
- Increases in pressure drop (↑ 5.6% – 14%) (SE0014705 and SE0014707)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The new products have ingredient and design differences to the filter components compared to the corresponding predicate products. However, these changes are in the non-combusted components of the tubes and are not expected to affect or alter smoke chemistry. TNCO smoke yields under ISO smoking regimen for the new products are either lower than or comparable to those for the corresponding predicate tobacco 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 product in SE0014707 meets statutory requirements because it was determined that it is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

Where an applicant supports a showing of SE by comparing the new tobacco product to a tobacco product that FDA previously found SE, in order to issue an SE order, FDA must find that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act).

The predicate tobacco products in SE0014705 and SE0014706 were previously determined to be substantially equivalent by FDA under SE0003200 and SE0012366, respectively. Comparison of the new tobacco products to the grandfathered products (Top Regular King Size in SE0003200 and Top Menthol King Size in SE0012366) reveals that the new tobacco products have the following differences in characteristics from Top Regular King Size and Top Menthol King Size, the grandfathered tobacco products:

- Ingredient changes to various filter components
 - Filter glue seam adhesive, filter plug wrap, tipping paper glue in the new tobacco products
 - Acetate tow (SE0014705)
 - Tipping paper (SE0014706)
- Decreases in tipping paper length and tube mass, and differences in filter density
- Differences in total denier and denier per filament (SE0014706)
- Increases in pressure drop (SE0014705)

The differences in characteristics listed above, other than the differences in total denier, denier per filament, and pressure drop are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0003200 and SE0012366. Therefore, these differences do not

cause the new tobacco products in SE0014705 and SE0014706 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in ingredients used in filter components such as the acetate tow, plug wrap, and tipping paper, and differences in tipping paper length between the new tobacco products in SE0014705 and SE0014706 and the grandfathered tobacco products do not cause the new tobacco products to raise different questions of public health. Therefore, whether comparing the new tobacco products in SE0014705 and SE0014706 to the predicate or grandfathered tobacco products, the new tobacco products do not raise different questions of public health.

The new tobacco products are currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude 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 these reviews 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 SE0014705, SE0014706, and SE0014707, as identified on the cover page of this review.