

**Technical Project Lead (TPL) Review:****SE0004347, SE0004349- SE0004354, SE0004356-
SE0004362, SE0004364, SE0004366, SE0004369-
SE0004374, SE0004378, and SE0004379**

SE0004347: Smoker Friendly Real Gold King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	35%
Characterizing Flavor	None
SE0004349: Smoker Friendly Real Regular King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None
SE0004350: Smoker Friendly Real Regular 100MM	
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None
SE0004351: 4 Aces Regular King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None
SE0004352: Largo Regular King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None

SE0004353: Admiral Regular King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None
SE0004354: Largo Gold King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	35%
Characterizing Flavor	None
SE0004356: Swift Laser Regular King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None
SE0004357: Largo Regular 100MM	
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Circumference	25,45 mm
Ventilation	None
Characterizing Flavor	None
SE0004358: High Card Gold King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	35%
Characterizing Flavor	None
SE0004359: 4 Aces Gold King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	35%
Characterizing Flavor	None

SE0004360: Admiral Gold King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	35%
Characterizing Flavor	None
SE0004361: Swift Laser Gold King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	35%
Characterizing Flavor	None
SE0004362: Admiral Regular 100MM	
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None
SE0004364: 4 Aces Regular 100MM	
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None
SE0004366: Swift Laser Regular 100MM	
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None
SE0004369: High Card Regular 100MM	
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None

SE0004370: High Card Regular King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None
SE0004371: Admiral Menthol King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	Menthol
SE0004372: Swift Laser Menthol King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	Menthol
SE0004373: 4 Aces Menthol King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	Menthol
SE0004374: High Card Menthol King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	Menthol
SE0004378: Largo Menthol King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	Menthol

SE0004379: Smoker Friendly Real Menthol King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	Menthol
Additional Information	
Applicant	Republic Tobacco, LP
Report Type	Regular
Product Category	Roll-Your-Own Tobacco Product
Product Sub-Category	Filtered paper tubes
Recommendation	
Issue Substantially Equivalent (SE) orders	

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman
-S
Date: 2014.11.06 14:01:58 -05'00'

Matthew R. Holman, 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 David Ashley -S
Date: 2014.11.06 14:18:45 -05'00'

David L. Ashley, Ph.D.
RADM, U.S. Public Health Service
Director,
Office of Science

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco products:

SE0004347: Smoker Friendly Real Gold King Size	
Product Name	Gambler Gold King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	35%
Characterizing Flavor	None
SE0004349: Smoker Friendly Real Gold 100MM	
Product Name	Gambler Regular King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None
SE0004350: Smoker Friendly Real Regular 100MM	
Product Name	Gambler Regular King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None
SE0004351: 4 Aces Regular King Size	
Product Name	Gambler Regular King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None

SE0004352: Largo Regular King Size	
Product Name	Gambler Regular King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None
SE0004353: Admiral Regular King Size	
Product Name	Gambler Regular King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None
SE0004354: Largo Gold King Size	
Product Name	Gambler Gold King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	35%
Characterizing Flavor	None
SE0004356: Swift Laser Regular King Size	
Product Name	Gambler Regular King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None
SE0004357: Largo Regular 100MM	
Product Name	Gambler Regular King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None

SE0004358: High Card Gold King Size	
Product Name	Gambler Gold King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	35%
Characterizing Flavor	None
SE0004359: 4 Aces Gold King Size	
Product Name	Gambler Gold King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	35%
Characterizing Flavor	None
SE0004360: Admiral Gold King Size	
Product Name	Gambler Gold King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	35%
Characterizing Flavor	None
SE0004361: Swift Laser Gold King Size	
Product Name	Gambler Gold King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	35%
Characterizing Flavor	None
SE0004362: Admiral Regular 100MM	
Product Name	Gambler Regular King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None

SE0004364: 4 Aces Regular 100MM	
Product Name	Gambler Regular King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None
SE0004366: Swift Laser Regular 100MM	
Product Name	Gambler Regular King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None
SE0004369: High Card Regular 100MM	
Product Name	Gambler Regular King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None
SE0004370: High Card Regular King Size	
Product Name	Gambler Regular King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	None
SE0004371: Admiral Menthol King Size	
Product Name	Top Menthol King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	Menthol

SE0004372: Swift Laser Menthol King Size	
Product Name	Top Menthol King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	Menthol
SE0004373: 4 Aces Menthol King Size	
Product Name	Top Menthol King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	Menthol
SE0004374: High Card Menthol King Size	
Product Name	Top Menthol King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	Menthol
SE0004378: Largo Menthol King Size	
Product Name	Top Menthol King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	Menthol
SE0004379: Smoker Friendly Real Menthol King Size	
Product Name	Top Menthol King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Circumference	25.45 mm
Ventilation	None
Characterizing Flavor	Menthol

The predicate tobacco products are manufactured by Republic Tobacco, LP.
The predicate products are 200-count boxes of roll-your-own filtered paper tubes.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant originally submitted these SE Reports in April 2012. The applicant submitted unsolicited amendments in July 2012 for some of the SE Reports. FDA sent the applicant administrative Advice and Information request letters (A/I letters) for all of the SE Reports in September 2012 and December 2012. In response to the administrative A/I letter, the applicant amended the SE Reports in October 2012 (SE0005022, SE0005024–SE0005029, SE0005031-SE0005036, SE0005038, SE0005040-SE0005044, and SE0005052) and in January 2013 (SE0006401, SE0006406-SE0006407, and SE0006409). FDA sent the applicant a scientific A/I letter in November 2013, and the applicant responded in January 2014 (SE0010125). FDA sent the applicant a Preliminary Finding letter in June 2014 and the applicant responded in July 2014 (SE0010583).

1.3. SCOPE OF REVIEW

This memo captures all administrative, compliance, and scientific reviews completed for SE0004347, SE0004349-SE0004354, SE0004356-SE0004362, SE0004364, SE0004366, SE0004369-SE0004374, SE0004378, and SE0004379.

2. ADMINISTRATIVE REVIEW

Administrative completeness reviews were completed by Daniel Gonski in September and December 2012 and by Daniel Gonski in February 2013 and Sarah Lee in May 2013.

The final completeness 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 as of February 15, 2007). The OCE reviews dated March 2013 conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are eligible predicate tobacco products.¹

The Office of Compliance and Enforcement (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

¹ Addendum reviews were completed in June 2013 to include the package type and size for the predicate and new tobacco products; the conclusions in these addendum reviews did not differ from that in the original May 2013 reviews.

the FD&C Act. The OCE review dated October 8, 2014, concludes that the predicate 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

Chemistry reviews were completed by Candice Jongsma on June 3, 2013, Jennifer Catalano on April 16, 2014, and Shixia Feng on October 8, 2014.

The final chemistry review concludes that the new tobacco products have different characteristics than the predicate tobacco products. Regarding product chemistry, the new tobacco products differ from the corresponding predicate tobacco products in that the amount of (b) (4) of new tobacco products is (b) (4) relative to the amount in the predicate tobacco products and the amount of (b) (4) of the new tobacco products is almost (b) (4) the amount in the predicate tobacco products. Because the (b) (4) is relatively small, it is not expected to impact (b) (4) performance. The (b) (4) may (b) (4) during smoking. However, the currently available data indicates that HPHC yields will either remain unchanged or (b) (4) rate. Therefore, the final chemistry review concludes that these differences in characteristics do not cause the new tobacco products to raise different questions of public health.

4.2. ENGINEERING

Engineering reviews were completed by Christian Coyle on June 3, 2013, and Komal Singh on April 16, 2014, and October 8, 2014.

The final engineering review concludes that the new tobacco products have different characteristics than the corresponding predicate tobacco products:

1. The new tobacco products in SE0004350, SE0004357, SE0004362, SE0004364, SE0004366, and SE0004369 have tube lengths of 100 mm whereas the tube lengths of the predicate tobacco products are 84 mm. The applicant adequately addressed the tube length concern using a study (b) (4)
2. The new tobacco products in SE0004350, SE0004357, SE0004362, SE0004364, SE0004366, and SE0004369 hav (b) (4)

(b) (4) compared to the corresponding predicate tobacco products, and all of the new tobacco products have (b) (4) compared to the corresponding predicate tobacco products. The applicant adequately addressed these differences using a study that (b) (4). The study adequately demonstrates that the above (b) (4) differences do not cause the new tobacco products to raise different questions of public health.

3. The new tobacco products in SE0004347, SE0004349, SE0004351-SE0004354, SE0004356, SE0004358-SE0004361, SE0004370-SE0004374, SE0004378, and SE0004379 have (b) (4) compared to the corresponding predicate tobacco products. The applicant adequately addressed this difference (b) (4). The study adequately demonstrates that the (b) (4) differences do not cause the new tobacco products to raise different questions of public health.

Therefore, the final engineering review concludes that these differences in characteristics do not cause the new tobacco products to raise different questions of public health.

4.3. TOXICOLOGY

Toxicology reviews were completed by Michael Orr on September 5, 2013, Michael Orr on June 9, 2014, and Luis Valerio on October 21, 2014.

The final toxicology review concludes that the new tobacco products have different characteristics than the predicate tobacco product, but the new tobacco products do not raise different questions of public health. The toxicology review considered (b) (4).

Therefore, from a toxicological standpoint, the (b) (4) does not cause the new tobacco products to raise different questions of public health. The toxicology review considered the (b) (4) of the new tobacco products. The toxicology review reached the same conclusion as the chemistry review on this issue. Therefore, the final toxicology review concludes that the differences in characteristics do not cause the new tobacco products to raise different questions of public health.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on November 5, 2014. The FONSI was supported by an environmental assessment prepared by FDA on October 29, 2014.

6. CONCLUSION AND RECOMMENDATION

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

- (b) (4)
-
-
-
-
- Increased tube lengths (from 84 mm to 100 mm)²

Although these differences exist, the applicants adequately demonstrated that the differences do not raise different questions of public health. The (b) (4) is relatively small and, therefore, not expected to impact (b) performance. (b) (4) do not cause the new tobacco products in these SE Reports to raise different questions of public health based on a study submitted in the SE Reports. The study demonstrates that the (b) (4) is no change in (b) (4) Increased tube lengths (from 84 mm to 100 mm) do not cause the new tobacco products in these SE Reports to raise different questions of public health based on a study submitted in the SE Reports combined with the (b) (4). The study demonstrates that there is (b) (4)

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. 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.

In addition, order letters can be issued because FDA examined the environmental effects of finding these new tobacco products substantially equivalent and made a finding of no significant impact.

² SE0004350, SE0004357, SE0004362, SE0004364, SE0004366, and SE0004369 only

TPL Review for SE0004347, SE0004349-SE0004354, SE0004356-SE0004362, SE0004364, SE0004366, SE0004369-SE0004374, SE0004378, and SE0004379

SE order letters should be issued for the new tobacco products in SE0004347, SE0004349-SE0004354, SE0004356-SE0004362, SE0004364, SE0004366, SE0004369-SE0004374, SE0004378, and SE0004379, as identified on the cover page of this review.