

**Technical Project Lead (TPL) Review: SE0012636, SE0012637, SE0012639, and SE0012641-SE0012644**

SE0012636: Swift Laser Menthol King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping paper from (b) (4) and (b) (4) from (b) (4)
SE0012637: High Card Menthol King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping paper from (b) (4) and (b) (4) from (b) (4)
SE0012639: Low Bob's Menthol King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping paper from (b) (4) and (b) (4) from (b) (4)
SE0012641: Largo Menthol King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping paper from (b) (4) and (b) (4) from (b) (4)

<b>SE0012642: Admiral Menthol King Size</b>	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping paper from (b) (4) and (b) (4) from (b) (4)
<b>SE0012643: 4 Aces Menthol King Size</b>	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping paper from (b) (4) and (b) (4) from (b) (4)
<b>SE0012644: Smoker Friendly Real Menthol King Size</b>	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping paper from (b) (4) and (b) (4) from (b) (4)
<b>Common Attributes of SE Reports</b>	
Applicant	Republic Tobacco, LP
Report Type	Regular
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Filtered Cigarette Tubes
<b>Recommendation</b>	
Issue Substantially Equivalent (SE) orders.	

**Technical Project Lead (TPL):**

Digitally signed by Colleen K. Rogers -S  
Date: 2018.06.05 11:11:10 -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: 2018.06.05 12:32:06 -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:

SE0012636: Swift Laser Menthol King Size	
Product Name	Swift Laser Menthol King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping paper from (b) (4) and (b) (4) from (b) (4)
SE0012637: High Card Menthol King Size	
Product Name	High Card Menthol King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping paper from (b) (4) and (b) (4) from (b) (4)
SE0012639: Low Bob's Menthol King Size	
Product Name	Low Bob's Menthol King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping paper from (b) (4) and (b) (4) from (b) (4)

SE0012641: Largo Menthol King Size	
Product Name	Largo Menthol King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping paper from (b) (4) and (b) (4) from (b) (4)
SE0012642: Admiral Menthol King Size	
Product Name	Admiral Menthol King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping paper from (b) (4) and (b) (4) from (b) (4)
SE0012643: 4 Aces Menthol King Size	
Product Name	4 Aces Menthol King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	None
Characterizing Flavor	Menthol
Additional Property	Tipping paper from (b) (4) and (b) (4) from (b) (4)
SE0012644: Smoker Friendly Real Menthol King Size	
Product Name	Smoker Friendly Real Menthol King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	None
Characterizing Flavor	Menthol
Additional Property	Tipping paper from (b) (4) and (b) (4) from (b) (4)

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

**1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW**

FDA received the SE Reports on November 16, 2015. FDA issued Acknowledgement letters on November 23, 2015. On June 27, 2016, FDA held a teleconference with the applicant requesting that Exhibit 14 from the original submission, which was illegible, be resubmitted. The applicant responded to this request by submitting amendment SE0013469 on June 30, 2016. FDA issued an Advice/Information Request (A/I) letter to the applicant on August 9, 2016. In response, the applicant submitted amendment SE0013716, which FDA received on September 30, 2016. FDA issued a Preliminary Finding letter on December 23, 2016. The applicant responded with amendment SE0013822, which FDA received on January 18, 2017. FDA issued an A/I letter to the applicant on February 26, 2018. FDA received a response on March 7, 2018 (SE0014570).

Product Name	SE Report	Amendments
Swift Laser Menthol King Size	SE0012636	SE0013469 SE0013716 SE0013822 SE0014570
High Card Menthol King Size	SE0012637	
Low Bob's Menthol King Size	SE0012639	
Largo Menthol King Size	SE0012641	
Admiral Menthol King Size	SE0012642	
4 Aces Menthol King Size	SE0012643	
Smoker Friendly Real Menthol King Size	SE0012644	

**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 November 20, 2015.

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

**3. COMPLIANCE REVIEW**

The predicate tobacco products were previously determined to be substantially equivalent by FDA as shown in the table below. Therefore, the predicate tobacco products are eligible predicate tobacco products.

SE Report	Predicate Tobacco Product Name	Predicate Tobacco Product Found SE Under:	SE Order Issue Date
SE0012636	Swift Laser Menthol King Size	SE0004372	November 7, 2014
SE0012637	High Card Menthol King Size	SE0004374	November 7, 2014
SE0012639	Low Bob's Menthol King Size	SE0010171	April 21, 2015
SE0012641	Largo Menthol King Size	SE0004378	November 7, 2014
SE0012642	Admiral Menthol King Size	SE0004371	November 7, 2014
SE0012643	4 Aces Menthol King Size	SE0004373	November 7, 2014
SE0012644	Smoker Friendly Real Menthol King Size	SE0004379	November 7, 2014

The Office of Compliance and Enforcement (OCE) completed reviews 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 reviews dated April 13, 2017; October 31, 2017; and May 17, 2018 conclude 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

Chemistry reviews were completed by Shixia Feng on August 4, 2016, and December 7, 2016.

The final chemistry review concludes that the new tobacco products have different characteristics compared to the corresponding predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health from a chemistry perspective. The review identified the following differences related to product composition:

- A change in supplier of (b) (4) and tipping paper
- Addition of the following ingredients to (b) (4)
  - (b) (4)
- Removal of the following ingredients from (b) (4)
  - (b) (4)
- An increase in the following tipping paper ingredients:
  - 5% increase in (b) (4)
  - 20% increase in (b) (4)
  - 38% increase in (b) (4)
- Slight modifications to the inks on the packaging (box)



The quantity of (b) (4) in the new tobacco products is identical to that in the corresponding predicate tobacco products; however, there are slight differences in the (b) (4) processing ingredients due to different suppliers. (b) (4) is a (b) (4) that is applied to the filter, a portion of the cigarette that is not combusted. The applicant provided test data for filter density and filter pressure drop, which demonstrate that the changes in the processing ingredients of the (b) (4) do not cause the new tobacco products to raise different questions of public health. Because tipping paper is not intended to undergo combustion during smoking and the concentrations of these ingredients are relatively small, it is not expected that the changes in tipping paper ingredients will cause the new tobacco products to raise different questions of public health. The changes to the container closure system (modification of inks) only affect the package design on the outside of the box (i.e., labeling) and are not expected to impact stability of the products. 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

Engineering reviews were completed by Komal Ahuja on July 29, 2016, and by Jim Melchior on November 22, 2016.

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

- A change in supplier of (b) (4) and tipping paper
- 2% increase in tipping paper length (0.5 mm)
- 1% decrease in total tube mass

The final engineering review concludes that no notable design parameter differences exist between the new and corresponding predicate tobacco products. The applicant provided all of the target specifications, upper and lower range limits, and test data for the applicable design parameters. The tipping paper in the new tobacco products is 0.5 mm longer than that in the corresponding predicate tobacco products. This increases the amount of tipping paper in the new tobacco products by 0.177 mg (less than 1/10 of 1% of the total tube mass of 198 mg). This change in tipping paper does not increase the overall length of the cigarette, and because tipping paper is not combusted during consumption, the change in tipping paper does not cause the new tobacco products to raise different questions of public health. 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.

#### 5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Hans Rosenfeldt, Ph.D. for Kimberly Benson, Ph.D. on June 4, 2018. The FONSI was supported by an environmental assessment prepared by FDA on June 4, 2018.

## 6. CONCLUSION AND RECOMMENDATION

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

- Tipping paper and (b) (4) from different suppliers
- 2% increase in tipping paper length (0.5 mm)
- 1% decrease in total tube mass
- Addition of the following ingredients to (b) (4)
  - (b) (4)
- Removal of the following ingredients from (b) (4)
  - (b) (4)
- An increase in the following tipping paper ingredients:
  - 5% increase in (b) (4)
  - 20% increase in (b) (4)
  - 38% increase in (b) (4)
- Slight modifications to the inks on the packaging (box)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The applicant is changing suppliers for (b) (4) and tipping paper and there are minor changes to these ingredients as a result. The quantity of (b) (4) in the new tobacco products is identical to that in the corresponding predicate tobacco products; however, there are slight differences in the processing ingredients. The applicant provided test data for filter density and filter pressure drop, which demonstrate that the changes to (b) (4) do not cause the new tobacco products to raise different questions of public health. Despite increases in some tipping paper ingredients, the changes are at low levels, which are not expected to increase HPHCs. Additionally, since tipping paper is not combusted in the process of cigarette consumption, it is unlikely that HPHCs will increase with these ingredient modifications. The slight increase in tipping paper length for the new tobacco products does not cause the new tobacco products to raise different questions of public health since it does not increase the overall cigarette length and the tipping paper is not combusted during cigarette consumption. 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.

The predicate tobacco products were previously determined to be substantially equivalent by FDA under SE0004372, SE0004374, SE0010171, SE0004378, SE0004371, SE0004373, and SE0004379. 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).

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<sup>1</sup> (b) (4) is a component of the cigarette filter.

The predicate tobacco products in SE0012636, SE0012637, and SE0012641-SE0012644 were previously determined to be substantially equivalent by FDA under SE0004372, SE0004374, SE0004378, SE0004371, SE0004373, and SE0004379, respectively. Comparison of the new tobacco products in SE0012636, SE0012637, and SE0012641-SE0012644 to the grandfathered tobacco product in SE0004372, SE0004374, SE0004378, SE0004371, SE0004373, and SE0004379 (Top Menthol King Size)<sup>2</sup> reveals the following differences in characteristics:

- Tipping paper and (b) (4) from different suppliers
- 2% increase in tipping paper length (0.5 mm)
- 5% decrease in pressure drop
- An increase in the following tipping paper ingredients:
  - 4% increase in (b) (4)
  - 19% increase in (b) (4)
  - 537% increase in (b) (4)
  - 6% increase in (b) (4)
  - 6% increase in (b) (4)

The differences in characteristics listed above, other than the difference in tipping paper and (b) (4) suppliers, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0004372, SE0004374, SE0004378, SE0004371, SE0004373, and SE0004379. Therefore, these differences do not cause the new tobacco products in SE0012636, SE0012637, and SE0012641-SE0012644 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in characteristics in the tipping paper and (b) (4) due to procurement from different suppliers between the new tobacco products in SE0012636, SE0012637, and SE0012641-SE0012644 and the grandfathered tobacco product do not cause the new tobacco products to raise different questions of public health. Therefore, whether comparing the new tobacco products in SE0012636, SE0012637, and SE0012641-SE0012644 to the predicate or grandfathered tobacco product, the new tobacco products do not raise different questions of public health.

The predicate tobacco product in SE0012639 was previously determined to be substantially equivalent by FDA under SE0010171. Comparison of the new tobacco product in SE0012639 to the grandfathered tobacco product in SE0010171 (Top Menthol King Size)<sup>3</sup> reveals the following differences in characteristics:

- Tipping paper and (b) (4) from different suppliers
- 2% increase in tipping paper length (0.5 mm)
- 5% decrease in pressure drop

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<sup>2</sup> Note that SE0004372, SE0004374, SE0004378, SE0004371, SE0004373, and SE0004379 use the same grandfathered tobacco product, Top Menthol King Size (UPC code 0-77170-26042-8).

<sup>3</sup> UPC code 0-77170-26042-8

- An increase in the following tipping paper ingredients:
  - 4% increase in (b) (4)
  - 21% increase in (b) (4)
  - 537% increase in (b) (4)
  - 6% increase in (b) (4)
  - 6% increase in (b) (4)

The differences in characteristics listed above, other than the difference in tipping paper and (b) (4) suppliers, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0010171. Therefore, these differences do not cause the new tobacco product in SE0012639 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in characteristics in the tipping paper and (b) (4) due to procurement from different suppliers between the new tobacco product in SE0012639 and the grandfathered tobacco product do not cause the new tobacco product to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0012639 to the predicate or grandfathered tobacco product, the new tobacco product does 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 SE0012636, SE0012637, SE0012639, and SE0012641-SE0012644, as identified on the cover page of this review.