

**Technical Project Lead (TPL) Review:  
SE0010167 – SE0010171**

<b>SE0010167: Low Bob's Regular 100 mm</b>	
Package Type	Box
Package Size	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
<b>SE0010168: Low Bob's Regular King Size</b>	
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
<b>SE0010169: Low Bob's Gold 100 mm</b>	
Package Type	Box
Package Size	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
<b>SE0010170: Low Bob's Gold King Size</b>	
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	35%
Characterizing Flavor	None
Additional Property	None
<b>SE0010171: Low Bob's Menthol King Size</b>	
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	None

<b>Common Attributes of SE Reports</b>	
Applicant	Republic Tobacco, LP
Report Type	Regular
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Cigarette Tube, Filtered
<b>Recommendation</b>	
Issue Substantially Equivalent (SE) orders.	

**Technical Project Lead (TPL):**

Digitally signed by Matthew R. Holman -S  
Date: 2015.04.21 15:50:39 -04'00'

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: 2015.04.21 15:51:57 -04'00'

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 PRODUCTS

The applicant submitted the following predicate tobacco products:

<b>SE0010167: Low Bob's Regular 100 mm</b>	
Product Name	Top Regular 100 mm
Package Type	Box
Package Size	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
<b>SE0010168: Low Bob's Regular King Size</b>	
Product Name	Gambler Regular King Size
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
<b>SE0010169: Low Bob's Gold 100 mm</b>	
Product Name	Top Gold 100 mm
Package Type	Box
Package Size	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
<b>SE0010170: Low Bob's Gold King Size</b>	
Product Name	Gambler Gold King Size
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	35%
Characterizing Flavor	None
Additional Property	None

<b>SE0010171: Low Bob's Menthol King Size</b>	
Product Name	Top Menthol King Size
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	None

The predicate tobacco products are Roll-Your-Own filtered cigarette tubes manufactured by the applicant.

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

The applicant originally submitted these SE Reports in February 2014. FDA sent the applicant a scientific advice and information request letter (scientific A/I letter) in August 2014, with a response due from the applicant within 60 days (i.e., by October 18, 2014). On October 14, 2014, the applicant submitted an amendment with its response to the scientific A/I letter (SE0010715). On December 23, 2014, FDA sent the applicant a Preliminary Finding letter indicating that deficiencies still existed and must be addressed within 30 days (i.e., by January 22, 2015). The applicant submitted an amendment with its response to the Preliminary Finding letter on January 21, 2015 (SE0010840).

<b>Product Name</b>	<b>SE Report</b>	<b>Amendments</b>
LOW BOB'S REGULAR 100MM	SE0010167	SE0010334 SE0010551 SE0010715 SE0010763 SE0010840
LOW BOB'S REGULAR KING SIZE	SE0010168	SE0010334 SE0010715 SE0010763 SE0010840
LOW BOB'S GOLD 100MM	SE0010169	SE0010334 SE0010551 SE0010715 SE0010763 SE0010840
LOW BOB'S GOLD KING SIZE	SE0010170	SE0010334 SE0010715 SE0010763 SE0010840
LOW BOB'S MENTHOL KING SIZE	SE0010171	SE0010334 SE0010715 SE0010763 SE0010840

### 1.3. SCOPE OF REVIEW

This memo captures all administrative, compliance, and scientific reviews completed for these SE Reports.

## 2. ADMINISTRATIVE REVIEW

Administrative completeness reviews were completed by Sarah Lee on March 21, 2014 and on March 31, 2014.

The final completeness reviews conclude that the SE Reports are administratively complete. Note that the initial reviews on March 21, 2014, conclude that the SE Reports are administratively incomplete because the applicant does not provide a statement about “other features” (section 910(a)(3)(B)). The final reviews on March 31, 2014, conclude that the SE Reports are administratively complete because amendment SE0010334 does, in fact, address “other features.”

## 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). OCE reviews dated April 30, 2014, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products in SE0010168, SE0010170, and SE0010171 are eligible predicate tobacco products. The predicate tobacco products in SE0010167 and SE0010169 were determined to be eligible predicate products because they were previously found substantially equivalent by FDA under SE0003200 and SE0003199, respectively.

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 the FD&C Act. The OCE reviews dated April 9, 2015, 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 Michael Morgan on August 6, 2014, and December 1, 2014, and by Tricia Johnson on March 6, 2015.

The final chemistry review concludes that the new tobacco product in SE0010171 has the same characteristics related to product composition as the corresponding predicate tobacco product. The final review also concludes that the new tobacco products in SE0010167 – SE0010170 have different characteristics related to product composition compared to the predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health. The following key differences in product composition between the new and corresponding tobacco predicate products were identified in the chemistry review:

- SE0010167:

(b) (4)

- SE0010168:

(b) (4)

- SE0010169:

(b) (4)

- SE0010170:

(b) (4)

The (b) (4) in ingredients within the (b) (4) in this case do not cause the new tobacco products to raise different questions of public health because these (b) (4). In addition, submitted HPHC data demonstrates that these ingredient changes do not adversely affect the (b) (4) of the new tobacco products relative to the predicate tobacco products. Th (b) (4)

The (b) (4) yields are comparable between the new and predicate tobacco products. The (b) (4) s could affect HPHC yields because these ingredients are combusted. However, submitted (b) (4) yields demonstrate that the (b) (4) s in these ingredients do not cause a (b) (4) yields. Therefore, the differences in characteristics related to product composition between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

#### 4.2. ENGINEERING

Engineering reviews were completed by Christopher Brown on August 6, 2014, by James Melchiors on December 3, 2014, and by Julie Morabito on March 5, 2015.

The final engineering review concludes that the new tobacco product in SE0010171 has the same characteristics related to product design as the corresponding predicate tobacco product. The final engineering review also 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 following keys differences in product design between the new and corresponding predicate tobacco products were identified in the chemistry review:

- SE0010167 and SE0010169:

(b) (4)



- SE0010168 and SE0010170:

(b) (4)

Because the (b) (4) yields are comparable between the new and corresponding predicate tobacco products, the differences in characteristics related to product design between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

#### **4.3. TOXICOLOGY**

A toxicology review was completed by Luis Valerio on December 10, 2014.

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 toxicology review addresses the differences in characteristics as raised and discussed in the chemistry review and concludes that the differences in characteristics related to product toxicology between the new and corresponding predicate tobacco products 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 Philip Yeager, Ph.D. on March 20, 2015. The FONSI was supported by an environmental assessment prepared by FDA on March 20, 2015.

#### **6. CONCLUSION AND RECOMMENDATION**

There are no differences in the characteristics of the new and predicate tobacco products in SE0010171. Therefore, the new tobacco product in SE0010171 is substantially equivalent to the predicate tobacco product.

The following are the key differences in characteristics between the new and corresponding predicate tobacco products in SE0010167 – SE0010170:

- SE0010167:

(b) (4)

- SE0010168:

(b) (4)

- SE0010169:

(b) (4)

- SE0010170:

(b) (4)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. In amendment SE0010840, the applicant shows that cigarettes prepared using the new and predicate tobacco products in SE0010167 – SE0010170 yield comparable <sup>(b) (4)</sup> yields. 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 products in SE0010168, SE0010170, and SE0010171 meet statutory requirements because they are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007). The predicate tobacco product in SE0010167 and SE0010169 was previously determined to be substantially equivalent by FDA under SE0003200 and SE0003199, respectively. Comparison of the new tobacco product in SE0010167 to the grandfathered product in SE0003200 (Top Regular King Size) reveals the following key differences in characteristics between the new tobacco product and Top Regular King Size, the grandfathered tobacco product (in addition to the differences identified above for the new tobacco products and the predicate tobacco product named by the applicant, Top Regular 100mm):

(b) (4)

All of these differences in characteristics are the same differences in characteristics which were originally identified for the new and grandfathered tobacco products in SE0003200. Therefore, these differences do not cause the new tobacco product to raise different questions of public health when comparing to the original grandfathered product.

Comparison of the new tobacco product in SE0010169 to the grandfathered product in SE0003199 (Top Gold King Size) reveals the following key differences in characteristics which were originally identified between the new tobacco product and Top Gold King Size, the grandfathered tobacco product (in addition to the differences identified above for the new tobacco products and the predicate tobacco product named by the applicant, Top Gold 100mm):

(b) (4)

All of these differences in characteristics are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0003199. Therefore, these differences do not cause the new tobacco product to raise different questions of public health when comparing to the original grandfathered product..

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 SE0010167 – SE0010171, as identified on the cover page of this review.