

## Technical Project Lead (TPL) Review: SE0012366

<b>SE0012366: TOP Menthol King Size</b>	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Width	8.1 mm
Filter Ventilation	(b) (4)
Characterizing Flavor	Menthol
Additional Property	Tipping paper 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 Tube
<b>Recommendation</b>	
Issue a Substantially Equivalent (SE) order.	

**Technical Project Lead (TPL):**

Digitally signed by Colleen K. Rogers -S  
Date: 2017.12.17 22:53:53 -05'00'

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: 2017.12.18 08:08:37 -05'00'

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 product:

SE0012366: TOP Menthol King Size	
Product Name	TOP Menthol King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Width	8.1 mm
Filter Ventilation	(b) (4)
Characterizing Flavor	Menthol
Additional Property	Tipping paper from (b) (4)

The predicate tobacco product is a roll-your-own filtered cigarette tube manufactured by the applicant.

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

On September 16, 2015, Republic Tobacco, LP submitted an SE Report for the tobacco product listed above. FDA acknowledged the report on September 29, 2015. On March 22, 2016, FDA emailed clarifying questions to the applicant. In response, the applicant submitted an amendment (SE0013042) on March 24, 2016.

Product Name	SE Report	Amendments
TOP Menthol King Size	SE0012366	SE0013042

**1.3. SCOPE OF REVIEW**

This review captures all regulatory, compliance, and scientific reviews completed for these SE Reports.

**2. REGULATORY REVIEW**

A regulatory review was completed by Sarah Webster on September 29, 2015.

The review concludes that the SE Report is 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 is a grandfathered product (i.e., was commercially marketed as of February 15, 2007). The OCE review dated October 25, 2016,

concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and, therefore, an eligible predicate tobacco product.

OCE completed reviews to determine whether the new tobacco product is 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 reviews dated February 23, 2016; April 11, 2016; July 27, 2016; October 14, 2016; April 21, 2017; and October 31, 2017, conclude that the new tobacco product is in compliance with the FD&C Act.

#### 4. SCIENTIFIC REVIEW

Scientific reviews<sup>1</sup> were completed by the Office of Science (OS) for the following discipline:

##### 4.1. CHEMISTRY

A chemistry review was completed by Jianping Gong on November 5, 2015.

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

- A change in supplier of triacetin and tipping paper
- An increase in the following tipping paper ingredients:
  - (b) (4) in cellulose
  - (b) (4) in calcium carbonate
  - (b) (4) in iron oxide yellow
- 0.5 mm increase in tipping paper length

The quantity of triacetin in the new tobacco product is identical to that in the predicate tobacco product; however, there are slight differences in the processing ingredients. Triacetin is a plasticizer 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 triacetin do not cause the new tobacco product to raise different questions of public health. The changes to ingredients in the tipping paper, which is not combusted in the process of consumption, in these amounts are unlikely to lead to changes in HPHC yields. The applicant stated that all of the design features of the new and predicate tobacco products are identical with the exception of tipping paper length. The tipping paper in the new tobacco product is 0.5 mm longer than that in the predicate tobacco product. This increases the amount of tipping paper in the new product by 0.178 mg (less than 1/10 of 1% of the total injector 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 product to raise different questions of public health. Therefore, the differences in characteristics between the new and predicate

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<sup>1</sup> Because the differences in characteristics were limited to two changes to material suppliers, the only scientific review needed was chemistry.

tobacco products does not cause the new tobacco product to raise different questions of public health from a chemistry perspective.

## 5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on October 31, 2017. The FONSI was supported by an environmental assessment prepared by FDA on October 31, 2017.

## 6. CONCLUSION AND RECOMMENDATION

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

- 0.5 mm increase in tipping paper length
- Increases in the following tipping paper ingredients:
  - (b) (4) in cellulose
  - (b) (4) in calcium carbonate
  - (b) (4) in iron oxide yellow

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. The applicant is changing suppliers for triacetin<sup>2</sup> and tipping paper and there are minor changes to these ingredients as a result. The quantity of triacetin in the new tobacco product is identical to that in the predicate tobacco product; 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 triacetin do not cause the new tobacco product 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 product does not cause the new tobacco product 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 predicate tobacco products do not cause the new tobacco product to raise different questions of public health.

The predicate tobacco product meets statutory requirements because it is a grandfathered product (i.e., was commercially marketed in the United States as of February 15, 2007).

The new tobacco product is currently in compliance with the FD&C Act. In addition, the chemistry review concludes that the differences between the new and predicate tobacco products are such that the differences do not cause the new tobacco product to raise different questions of public health. I concur with the review and recommend that an SE order letter be issued.

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<sup>2</sup> Triacetin is a component of the cigarette filter.

FDA examined the environmental effects of finding this new tobacco product substantially equivalent and made a finding of no significant impact.

An SE order letter should be issued for the new tobacco product in SE0012366, as identified on the cover page of this review.