

**Technical Project Lead (TPL) Review:
SE0014665 and SE0014668**

SE0014665: Top McClintock Blue King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.2 mm
Ventilation	35%
Characterizing Flavor	None
SE0014668: Top McClintock Regular King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.2 mm
Ventilation	0%
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Republic Tobacco, LP
Report Type	Regular
Product Category	Roll-Your-Own Tobacco Products
Product Sub-Category	Filtered Cigarette Tube
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Jeannie Jeong-Im, 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)

Matthew R. Holman, Ph.D.
Director
Office of Science

TABLE OF CONTENTS

1. BACKGROUND	4
1.1. PREDICATE TOBACCO PRODUCTS	4
1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW	5
1.3. SCOPE OF REVIEW	5
2. REGULATORY REVIEW	5
3. COMPLIANCE REVIEW	5
4. SCIENTIFIC REVIEW	5
4.1. CHEMISTRY	5
4.2. ENGINEERING	6
5. ENVIRONMENTAL DECISION	7
6. CONCLUSION AND RECOMMENDATION	7

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0014665: Top McClintock Blue King Size	
Product Name	200CT GAMBLER REG TUBE
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.2 mm
Ventilation	0%
Characterizing Flavor	None
SE0014668: Top McClintock Regular King Size	
Product Name	200CT GAMBLER REG TUBE
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.2 mm
Ventilation	0%
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 April 30, 2018 FDA received two SE Reports (SE0014665 and SE0014668) from Republic Tobacco, LP. FDA issued Acknowledgement letters to the applicant on May 4, 2018. FDA issued an Advice and Information Request (A/I) letter for SE0014665 on July 6, 2018. FDA received the applicant's response (SE0014823) to the A/I letter on July 19, 2018.

Product Name	SE Report	Amendments
Top McClintock Blue King Size	SE0014665	SE0014823
Top McClintock Regular King Size	SE0014668	N/A

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 4, 2018.

The 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 in SE0014665 and SE0014668 are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews dated May 31, 2018, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered and, therefore 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 reviews dated July 5, 2018, and October 10, 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

Chemistry reviews were completed by Caroline Agarabi on June 25, 2018 for SE0014665 and SE0014668 and on September 11, 2018 for only SE0014665.

The final chemistry review did not identify any significant differences in characteristics between the new and predicate tobacco products in SE0014668 that could cause the new tobacco product to raise different questions of public health from a chemistry perspective. Additionally, the final chemistry review also concludes that the new tobacco product in SE0014665, has different characteristics related to product chemistry compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- 506% increase in (b) (4) in the tipping papers for SE0014665
- Increase in filter ventilation from 0% to 35% for SE0014665

The new and predicate products are composed of identical materials with only minor differences in ingredients for SE0014665. This includes an increase in the amount of (b) (4) e used in the tipping paper, a non-combusted portion of the tube, in the new product as compared to the predicate product for SE0014665. As a result of the quantity and location of this ingredient in the non-combusted portion of the tobacco product, the increase in this ingredient does not cause the new product to raise different questions of public health. In addition, for SE0014665, the new product contained a 35% filter ventilation whereas the predicate products had none which will be discussed further below in section 4.2: engineering. However, to demonstrate this difference does not cause the new product to raise different questions of public health, the applicant submitted TNCO data for the new and predicate products subject of SE0014665 using an identical RYO tobacco blend. The TNCO yields decreased in the new product compared to the predicate tobacco product. These TNCO data support that the filter ventilation increase between the new and predicate products in SE0014665 does not cause the new tobacco product 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 a chemistry perspective.

4.2. ENGINEERING

Engineering reviews were completed by Robert Meyer on June 22, 2018 for SE0014665 and SE0014668 and on September 12, 2018 for only SE0014665.

The final engineering review concludes that the new tobacco products in SE0014665 and SE0014668 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:

- 100% increase in tube paper base paper porosity, increase to 35% from 0% in ventilation, and 11% decrease in total denier for SE0014665
- 7% decrease in tube mass and 11% decrease in total denier for SE0014668

The new and corresponding predicate products contain differences in product design parameters; however, these differences do not cause the new products to raise different questions of public health. Specifically, for SE0014665, the new and predicate products differ in base paper porosity (↑100%), increase in ventilation (from 0% to 35%), and total denier

(↓11%). From an engineering perspective, a more porous cigarette paper and increase in ventilation allows environmental air to enter the smoke stream, which will reduce smoke constituents. For SE0014668, the new and predicate tobacco products decrease in tube mass (↓7%) and total denier (↓11%). TNCO yields from the new products in SE0014665 and SE0014668 are lower than the corresponding predicate products, demonstrating that the filter changes do not cause the new 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 Kimberly Benson, Ph.D. on August 30, 2018. The FONSI was supported by an environmental assessment prepared by FDA on August 29, 2018.

6. CONCLUSION AND RECOMMENDATION

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

- 506% increase in (b) (4) in the tipping papers for SE0014665
- 100% increase in tube paper base paper porosity, increase to 35% from 0% in ventilation, and 11% decrease in total denier for SE0014665
- 7% decrease in tube mass and 11% decrease in total denier for SE0014668

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 product of SE0014665, increased in the amount of (b) (4) in the tipping paper by 506%. The tipping paper is not combusted and does not result in increased TNCO yields (decreased by 50% – 95%). For SE0014665, the base paper porosity and ventilation increased, which allows more environmental air to enter the smoke stream and may reduce HPHCs. However, the total denier decreased, which may reduce filter efficiency. Through filter pressure drop evaluation, the new product of SE0014665 did not result in a less efficient filter. In SE0014668, the tube mass and total denier both decreased, which may decrease the filter efficiency and cause an increase in smoke constituents. However, the functional pressure drop testing adequately demonstrated the filter functionality is improved. 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 meet statutory requirements because it was determined that they are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

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 SE0014665 and SE0014668, as identified on the cover page of this review.