

Technical Project Lead (TPL) Review: SE0015552, SE0015557, and SE0015559

SE0015552: Top McClintock Menthol King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.2 mm
Ventilation	None
Characterizing Flavor	Menthol
SE0015557: Top McClintock Blue King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.2 mm
Ventilation	35%
Characterizing Flavor	None
SE0015559: Top McClintock Blue 100 mm	
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.2 mm
Ventilation	None
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Republic Tobacco, LP
Report Type	Regular
Product Category	Roll-Your-Own
Product Sub-Category	Filtered Cigarette Tube
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Jeannie H. Jeong-im -S
Date: 2020.05.05 12:04:54 -04'00'

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)

Digitally signed by Matthew R. Holman -S
Date: 2020.05.05 14:54:30 -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:

SE0015552: Top McClintock Menthol King Size	
Product Name	Top McClintock Menthol King Size
Package Type	Box
Portion Count	200 tubes
Length	84 mm
Diameter	8.2 mm
Ventilation	None
Characterizing Flavor	Menthol
SE0015557: Top McClintock Blue King Size	
Product Name	Top McClintock Blue King Size
Package Type	Box
Portion Count	200 tubes
Length	84 mm
Diameter	8.2 mm
Ventilation	35%
Characterizing Flavor	None
SE0015559: Top McClintock Blue 100 mm	
Product Name	Top McClintock Blue 100MM
Package Type	Box
Portion Count	200 tubes
Length	100 mm
Diameter	8.2 mm
Ventilation	None
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 November 1, 2019, November 4, 2019, and November 5, 2019, FDA received SE0015552, SE0015557, and SE0015559, respectively, from Republic Tobacco, LP. FDA issued Acceptance letters on November 5, 2019 for SE0015552 and November 7, 2019 for SE0015557 and SE0015559. On January 3, 2020, FDA issued a Deficiency letter. On February 6, 2020, FDA received the applicant's response to the Deficiency letter (SE0015684).

Product Name	SE Report	Amendments
Top McClintock Menthol King Size	SE0015552	SE0015684
Top McClintock Blue King Size	SE0015557	
Top McClintock Blue 100 mm	SE0015559	

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 Donna Cheung on November 5, 2019 for SE0015552 and November 7, 2019 for SE0015557 and SE0015559.

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

3. COMPLIANCE REVIEW

The predicate tobacco products in SE0015552, SE0015557, and SE0015559 were 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	Predicate Tobacco Product Found SE Under:	Date
SE0015552	TOP Menthol King Size	SE0012366	December 18, 2017
SE0015557	Top Regular King Size	SE0003200	September 26, 2013
SE0015559	Top Gold King Size	SE0003199	September 26, 2013

The Office of Compliance and Enforcement (OCE) 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 review dated April 30, 2020 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 Melis Coraggio on December 19, 2019 and Jason Hsieh on April 1, 2020.

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

SE0015552 - Tipping paper is 1.35% (0.33 mg/tube) less in the new products

- Tipping paper ingredients:
 - 11.6% (b) (4) mg/tube) less (b) (4)
 - 96.3% (b) (4) mg/tube) less (b) (4)
 - 41.2% (b) (4) mg/tube) more (b) (4)
 - 63.6% (b) (4) mg/tube) more (b) (4)
 - 91.7% (b) (4) mg/tube) less (b) (4)
 - 1400% (b) (4) mg/tube) more of (b) (4)
 - addition of (b) (4) mg, (b) (4)
 - deletion of (b) (4) mg, (b) (4)

SE0015557 & SE0015559 - Tipping paper is 0.69% higher in the new products

- Tipping paper ingredients:
 - (b) (4) mg/tube addition of (b) (4)
 - (b) (4) and (b) (4) (SE0015559 only)

The applicant provided a complete list of ingredients for the new and corresponding predicate tobacco products. The new products are identical in composition, with the exception of the tipping paper. The ingredient changes in the tipping paper are minor (<1.6 mg/tube). As this portion of the tobacco product is not intended to be combusted, no additional harmful and potentially harmful constituents (HPHCs) besides tar, nicotine, and carbon monoxide (TNCO) are needed. The applicant submitted TNCO smoke data obtained under ISO and CI smoking regimens for the new and predicate products using an identical RYO tobacco blend with target quantities corresponding to the tube fill volume. The TNCO differences were determined to either be analytically equivalent or lower in the new tobacco products as compared to the corresponding predicate tobacco products. Therefore, the differences in TNCO do not 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

An engineering review was completed by Raymond Williamson on December 19, 2019.

The engineering review did not identify any differences in characteristics between the new and corresponding predicate tobacco products, except for a <1% decrease in cigarette paper band space in SE0015552, that could cause the new tobacco products to raise different questions of public health from an engineering perspective. 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 related to product engineering.

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by William Brenner on December 10, 2019 and April 13, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 20, 2020. The FONSI was supported by an environmental assessment prepared by FDA on April 20, 2020.

6. CONCLUSION AND RECOMMENDATION

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

SE0015552 - Tipping paper is 1.35% (0.33 mg/tube) less in the new products

- Tipping paper ingredients:
 - 11.6% (b) (4) mg/tube) less (b) (4)
 - 96.3% (b) (4) mg/tube) less (b) (4)
 - 41.2% (b) (4) mg/tube) more (b) (4)
 - 63.6% (b) (4) mg/tube) more (b) (4)
 - 91.7% (b) (4) mg/tube) less (b) (4)
 - 1400% (b) (4) mg/tube) more of (b) (4)
 - addition of (b) (4) mg (b) (4)
 - deletion of (b) (4) mg (b) (4)
- Cigarette paper band space decrease (<1%)

SE0015557 & SE0015559 - Tipping paper is 0.69% higher in the new products

- Tipping paper ingredients:
 - (b) (4) mg/tube addition of (b) (4)
 - (b) (4) and (b) (4) (SE0015559 only)

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 tobacco products are identical in composition, with the exception of the tipping paper, to the corresponding predicate tobacco products. The ingredient changes in the tipping paper are minor (<1.6 mg/tube). As this portion of the tobacco product is not intended to be combusted and has not resulted in increased TNCO yields. The TNCO differences were determined to either be analytically equivalent or lower in the new tobacco products. 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 SE0015552, SE0015557 and SE0015559 were previously determined to be substantially equivalent by FDA under SE0014667, SE0014675, and SE0014674, respectively.

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).

The predicate tobacco products in SE0015552, SE0015557, and SE0015559 were previously determined to be substantially equivalent by FDA under SE0012366, SE0003200, and SE0003199, respectively. Comparison of the new tobacco products to the grandfathered products (TOP Menthol King Size in SE0012366, Top Regular King Size in SE0003200, and Top Gold King Size in SE0003199) reveals that the new tobacco products have the following differences in characteristics from TOP Menthol King Size, Top Regular King Size, and Top Gold King Size, the grandfathered tobacco products:

The new tobacco product has the following key differences in product design compared to the corresponding grandfathered tobacco product:

SE0015552

- Filtered tube mass decrease (6%)
- Filter total denier decrease (6%)
- Filter denier per filament decrease (14%)
- Filter density decrease (6%)

SE0015557

- Tube paper base paper porosity increase (100%)
- Filter total denier decrease (11%)
- Filter denier per filament decrease (5%) Filter ventilation increase (non-ventilated to 35%)
- Filter pressure drop increase (6%)

SE0015559

- Filtered tube length increase (19%)
- Filtered tube mass increase (34%)
- Tipping paper length increase (8%)
- Tube paper base paper basis weight increase (6%)
- Tube paper base paper porosity increase (93%)
- Filter total denier decrease (13%)
- Filter denier per filament increase (32%)
- Filter length increase (67%)

The differences in characteristics listed above, other than the differences in tipping paper, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0012366, SE0003200, and SE0003199. Therefore, these differences do not cause the new tobacco products in SE0015552, SE0015557, and SE0015559 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in filter tube mass, filter tube mass, filter total denier per filament, filter density, tube paper base paper base weight and porosity, and filter length between the new tobacco products in SE0015552, SE0015557, and SE0015559 and the grandfathered tobacco products do not cause the new tobacco products to raise different questions of public health. Therefore, whether comparing the new tobacco products in SE0015552, SE0015557, and SE0015559 to the predicate of grandfathered tobacco products, the new tobacco products do 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 SE0015552, SE0015557, and SE0015559, as identified on the cover page of this review.