FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review:

SE0014666, SE0014667, SE0014674, and SE0014675

SE0014666: Top McClintock Regular 100MM	
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.2 mm
Ventilation	0%
Characterizing Flavor	None
SE0014667: Top McClintock Menthol King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.2 mm
Ventilation	0%
Characterizing Flavor	Menthol
SE0014674: Top McClintock Blue 100MM	
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.2 mm
Ventilation	0%
Characterizing Flavor	None
SE0014675: Top McClintock Blue King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.2 mm
Ventilation	35%
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):

Digitally signed by Matthew J. Walters -S
Date: 2019.04.15 14:50:48 -04'00'

Matthew J. Walters, Ph.D., MPH
CDR, U.S. Public Health Service
Deputy 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)

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Date: 2019.04.15 15:56:27 -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:

SE0014666: Top McClintock Regular 100MM	
Product Name	Top Regular 100MM
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.2 mm
Ventilation	0%
Characterizing Flavor	None
SE0014667: Top McClintock Menthol King Size	
Product Name	Top Menthol King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.2 mm
Ventilation	0%
Characterizing Flavor	Menthol
SE0014674: Top McClintock Blue 100MM	
Product Name	Top Gold 100MM
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.2 mm
Ventilation	0%
Characterizing Flavor	None
SE001467S: Top McClintock Blue King Size	
Product Name	Top Regular 100MM
Package Type	Box
Package Quantity	200 tubes
Length	100 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 four SE Reports (SE0014666, SE0014667, SE0014674, and SE0014675) from Republic Tobacco, LP. On May 4, 2018, FDA issued Acknowledgement letters to the applicant. On July 6, 2018, FDA issued an Advice and Information Request letter to the applicant. The applicant submitted an amendment (SE0014823) which FDA received on July 19, 2018. FDA issued a Preliminary Finding letter on October 18, 2018. The applicant submitted an amendment (SE0015063) which FDA received on January 16, 2019.

Product Name	SE Report	Amendments
Top McClintock Regular 100MM	SE0014666	SE0014823 SE0015063
Top McClintock Menthol King Size	SE0014667	
Top McClintock Blue 100MM	SE0014674	
Top McClintock Blue King Size	SE0014675	

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 predicate tobacco product in SE0014666 and SE0014675 was determined to be substantially equivalent by FDA under SE0003200. Additionally, the predicate tobacco products in SE0014667 and SE0014674 were determined to be substantially equivalent by FDA under SE0012366 and SE0003199, respectively. Therefore, these products 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 review dated April 3, 2019 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, and September 11, 2018. Additionally, Selena Russell completed a chemistry review on March 22, 2019 to address the statutory requirement that 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 (grandfathered (GF) product) (see section 910(a)(2)(A)(i)(I) of the FD&C Act).

The second chemistry review (September 11, 2018) 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:

- SE0014666
  - 49% decrease in glue seam/filter total weight
  - 75% decrease in (b) (4)
  - 37% decrease in (b) (4) in the wrapper of the plugwrap
  - 76% increase in (b) (4) processing aid for the plugwrap
  - 33% increase in (b) (4) processing aid for acetate tow
  - 90% decrease in (b) (4) plasticizer
  - 33% decrease in the tipping glue
- SE0014667
  - 990% increase in the (b) (4) color in the tipping paper
  - 629% increase in the (b) (4)
  - 93% decrease in (b) (4) in the starch binder
  - 42% decrease in glue seam/filter total weight
  - 71% decrease in (b) (4)
  - 33% decrease in (b) (4) for plugwrap
  - 90% decrease in (b) (4) plasticizer
  - 33% decrease in glue filter hot melt
  - 57% decrease glue filter adhesive
  - 22% decrease in the tipping glue
- SE0014674
  - 49% decrease in glue seam/filter total weight
  - 75% decrease in (b) (4)
  - 37% decrease in (b) (4) in the wrapper of the plugwrap
  - 76% increase in (b) (4) processing aid for the plugwrap
  - 46% decrease in glue filter hot melt
  - 50% decrease in total ink
  - 33% decrease in the tipping glue

- SE0014675
  - 445% increase in (b) (4) in the tipping paper wrapper
  - 18% decrease in (b) (4) filler of the tipping paper
  - 19% decrease in (b) (4) binder of the tipping paper
  - 1100% increase in the (b) (4) of the tipping paper
  - 90% decrease in (b) (4) of the tipping paper
  - 62% decrease in glue seam/filter total weight
  - 81% decrease in (b) (4)
  - 41% decrease in the plugwrap
  - 62% decrease in the (b) (4) filler
  - 34% overall decrease in the acetate tow
  - 43% overall decrease in the (b) (4)
  - 68% decrease in glue filter hot melt
  - 43% decrease in glue filter adhesive
  - 50% decrease in total ink
  - 38% decrease in the tipping glue

The new and corresponding predicate products are composed of similar materials with only slight differences in ingredients for SE0014667 and SE0014675. This includes increases in the amounts of (b) (4) (both SE0014667 and SE0014675), (b) (4) (SE0014667 only), and (b) (4) (SE0014675 only) used in the tipping papers, a non-combusted portion of the tubes, in the new products as compared to the corresponding predicate products. As a result of the quantities and location of these ingredients in the non-combusted portion of the tobacco product, the increases in these ingredients do not cause the new products to raise different questions of public health. All other ingredients decreased which do not cause a concern from the perspective of chemistry. In addition, for SE0014675, 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 products to raise different questions of public health, the applicant submitted TNCO data for the new and predicate products (previously found SE) for this product as well as for SE0014666 and SE0014674 using an identical RYO tobacco blend. The TNCO yields decreased in all new products compared to the corresponding predicate tobacco products. These TNCO data support that the 35% filter ventilation increase between the new and corresponding predicate product in SE0014675 does not cause the new 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, and on September 12, 2018.

The final engineering review did not identify any differences in characteristics between the new and predicate tobacco products in SE0014674 that could cause the new tobacco products to raise different questions of public health from an engineering perspective. Additionally, the final engineering review also concludes that the new tobacco products in

SE0014666, SE0014667, and SE0014675 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:

- SE0014666:
  - 14% increase in filter pressure drop
  - 7% increase in filter density

- SE0014667:
  - 6% decrease in tube mass
  - 14% decrease in denier per filament
  - 6% decrease in filter density
  - 6% decrease in total denier

- SE0014674
  - 49% decrease in glue seam/filter total weight
  - 75% decrease in (b) (4)
  - 37% decrease in (b) (4) in the wrapper of the plugwrap
  - 76% increase in (b) (4) processing aid for the plugwrap\46% decrease in glue filter hot melt
  - 50% decrease in total ink
  - 33% decrease in the tipping glue

- SE0014675:
  - 16% decrease in length
  - 14% decrease in tipping paper length
  - 35% increase in ventilation
  - 100% increase in base paper porosity
  - 28% decrease in tube mass
  - 28% decrease in filter denier per filament
  - 7% increase in filter density
  - 10% in decrease filter pressure drop
  - 40% decrease filter length

The new and corresponding predicate products contain differences in product design parameters for SE0014666, SE0014667, and SE0014675; however, these differences do not cause the new products to raise different questions of public health. Specifically, for SE0014666, the new and predicate products differ in pressure drop (↑14%) and filter density (↑7%), both of which are known to increase filter efficiency, which may result in a decrease in HPHC smoke yields. The applicant submitted TNCO data (explained below) which further indicates that these differences do not cause the new product to raise different questions of public health. For SE0014667, the new and predicate products differ in filter denier per filament (↓14%), which may trap less smoke constituents. TNCO yields from the new product in SE0014667 are lower than the corresponding predicate product, demonstrating that the filter changes do not cause the new product to raise different questions of public health. For SE0014675, there are many key design parameter

differences between the new and predicate products; however, this is primarily due to the decrease in the length (100mm vs 84mm) of the new product. TNCO yields from the new product in SE0014675 are lower than the predicate product, demonstrating that these changes do not cause the new product to raise different questions of public health. In addition, for SE0014675, the new product contained a 35% filter ventilation whereas the predicate products had none. The applicant demonstrated that this difference does not cause the new product to raise different questions of public health by submitting test data from 30 samples which demonstrated all results are within the established range limits confirming consistent manufacturing. Additionally, TNCO data for the new and predicate products (previously found SE) for this product as well as for SE0014666 and SE0014674 was submitted using an identical RYO tobacco blend. The TNCO yields decreased in all new products compared to the corresponding predicate tobacco products. These TNCO data also support that the 35% filter ventilation increase between the new and corresponding predicate product in SE0014675 does not cause the new 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 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:

- SE0014666:
  - 49% decrease in glue seam/filter total weight
  - 75% decrease in (b) (4) [redacted]
  - 37% decrease in (b) (4) [redacted] in the wrapper of the plugwrap
  - 76% increase in (b) (4) [redacted] processing aid for the plugwrap
  - 33% increase in (b) (4) [redacted] processing aid for acetate tow
  - 90% decrease in (b) (4) [redacted] plasticizer
  - 33% decrease in the tipping glue
  - 14% increase in filter pressure drop
  - 7% increase in filter density

- SE0014667:
  - 990% increase in the (b) (4) [redacted] color in the tipping paper
  - 629% increase in the (b) (4) [redacted]
  - 93% decrease in (b) (4) [redacted] in the starch binder
  - 42% decrease in glue seam/filter total weight
  - 71% decrease in (b) (4) [redacted]
  - 33% decrease in (b) (4) [redacted] for plugwrap

- 90% decrease in (b) (4) plasticizer
- 33% decrease in glue filter hot melt
- 57% decrease glue filter adhesive
- 22% decrease in the tipping glue
- 6% decrease in tube mass
- 14% decrease in denier per filament
- 6% decrease in filter density
- 6% decrease in total denier

- SE0014675:
  - 445% increase in (b) (4) in the tipping paper wrapper
  - 18% decrease in (b) (4) filler of the tipping paper
  - 19% decrease in (b) (4) binder of the tipping paper
  - 1100% increase in the (b) (4) of the tipping paper
  - 90% decrease in (b) (4) of the tipping paper
  - 62% decrease in glue seam/filter total weight
  - 81% decrease in (b) (4)
  - 41% decrease in the plugwrap
  - 62% decrease in the (b) (4) filler
  - 34% overall decrease in the acetate tow
  - 43% overall decrease in the (b) (4)
  - 68% decrease in glue filter hot melt
  - 43% decrease in glue filter adhesive
  - 50% decrease in total ink
  - 38% decrease in the tipping glue
  - 16% decrease in length
  - 14% decrease in tipping paper length
  - 35% increase in ventilation
  - 100% increase in base paper porosity
  - 28% decrease in tube mass
  - 28% decrease in filter denier per filament
  - 7% increase in filter density
  - 10% in decrease filter pressure drop
  - 40% decrease filter length

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. For SE0014674, there were only slight differences between the new and predicate products, however, these differences do not cause the new products to raise different questions of public health. The new products of SE0014667 and SE0014675 increased in the amount of (b) (4), (b) (4) (SE0014667 only), and (b) (4) (SE0014675 only) in the tipping paper by 445 – 990%, 629%, and 1100%, respectively. The tipping paper is not combusted and does not result in increased TNCO yields (decreased by 50 – 95%). For SE0014666, the filter pressure drop increased, which may increase the overall filter efficiency resulting in better filtration of HPHC smoke yields. Filter denier per filament decreased in the new product of SE0014667, which may cause the new product to trap less smoke constituents. However, the TNCO quantities for SE0014667 are reduced (3 – 17%) for the new product compared to the

corresponding predicate product. For SE0014675, there were many key design parameters that changed due to the decrease in length from 100mm to 84mm. The new product decreases in tube mass (28%), filter length (40%), filter pressure drop (10%), and tipping paper length (14%). These decreases may result in an increase of smoke constituents as the filter is less efficient. However, the tube paper base paper porosity increased by 100% and ventilation increased to 35% from 0%. Also, the TNCO values indicate there is a 45 – 69% reduction in TNCO for SE0014675. 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 product in SE0014666 and SE0014675 was determined to be substantially equivalent by FDA under SE0003200. Additionally, the predicate tobacco products in SE0014667 and SE0014674 were determined to be substantially equivalent by FDA under SE0012366 and SE0003199, 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 SE0014666 and SE0014675 were previously determined to be substantially equivalent by FDA under SE0003200, and SE0014667 and SE0014674 were previously determined to be substantially equivalent by FDA under SE0012366 and SE0003199, respectively. Comparison of the new tobacco products to the grandfathered products (Top Regular King Size in SE0003200, Top Menthol King Size in SE0012366, and Top Gold King Size in SE0003199) reveals that the new tobacco products have differences in characteristics from Top Regular King Size, Top Menthol King Size, and Top Gold King Size, the grandfathered tobacco products:

<u>SE0014666</u>

- 20% increase in cigarette paper weight
- 29% increase in (b) (4) in the cigarette paper
- 33% decrease in glue seam/filter total weight
- 67% decrease in (b) (4)
- 68% increase in plugwrap total weight
- 88% increase in (b) (4)
- 59% increase in acetate tow total weight
- 60% increase in (b) (4)
- 24% decrease in total tipping glue
- 19% increase in filter tube length
- 35% increase in filter tube mass
- 32% increase in denier per filament
- 13% decrease in total denier
- 33% increase in pressure drop
- 67% increase in filter length
- 67% increase in filter length

The differences in characteristics between SE0014666 and the grandfathered product subject of SE003200, except for acetate tow total weight (due to an increase in (b) (4)), filter tube length,

and filter pressure drop, are smaller in magnitude than the changes in these characteristics between the previously found SE product (SE0003200) and the predicate product. The 59% increase in acetate tow weight (due to an increase in (b) (4)) is likely due to the increase in filter length which would increase the efficiency of the filter and result in lower yields of HPHCs. Also, in general, increases in filter pressure drop may also increase filtration efficiency and therefore the 14% increase in filter pressure drop may decrease smoke constituent yields. However, the 20% increase in cigarette paper weight, as a result of the 28% increase in (b) (4) in the paper, has the possibility to offset a decrease in smoke constituent yields due to filter pressure drop. The applicant provided TNCO yields between the new and grandfathered product which showed a slight increase in nicotine and carbon monoxide, but these increases are within the variability of the measurements. Thus, the differences in characteristics between the new and the grandfathered product do not cause the new product to raise different questions of public health.

SE0014667

- 27% increase in (b) (4) in the tipping paper
- 42% decrease in glue seam/filter
- 71% decrease in (b) (4)
- 12% decrease in (b) (4)
- 22% decrease in tipping glue
- 14% decrease in denier per filament

The differences in characteristics between SE0014667 and the grandfathered product subject of SE0012366 are smaller in magnitude or identical to the changes in characteristics between the previously found SE product (SE0012366) and the predicate product, except for a 14% decrease in denier per filament. The applicant provided TNCO yields between the new and grandfathered product which showed a reduction in TNCO yields which demonstrated that these differences do not impact the TNCO yields between the new and grandfathered tobacco products. Thus, the differences in characteristics between the new and the grandfathered product do not cause the new product to raise different questions of public health.

SE0014674

- 20% increase in cigarette paper
- 17% increase in (b) (4)
- 11% increase in (b) (4)
- 34% decrease in glue seam/filter total weight
- 67% decrease in (b) (4)
- 66% increase in plugwrap total weight
- 86% increase in (b) (4)
- 57% increase in acetate tow total weight
- 58% increase in (b) (4)
- 26% increase in water
- 25% decrease in tipping glue
- 19% increase in filter tube length
- 35% increase in filter tube mass
- 93% increase in base paper porosity
- 13% decrease in total denier
- 32% increase in denier per filament

- 67% increase in filter length

The differences in characteristics between SE0014674 and the grandfathered product subject of SE0003199, except for glue seam/filter total weight (due to an increase in (b) (4)), (b) (4) in the plug wrap, acetate tow total weight (due to increases in (b) (4) and (b) (4)), and tipping glue total weight, are smaller in magnitude or identical to the changes in these characteristics between the previously found SE product (SE0003199) and the predicate product. However, these changes may have an influence on TNCO smoke yields when comparing the new product to that of the grandfathered product. The applicant provided TNCO yields between the new and grandfathered product which showed a reduction in TNCO yields which demonstrated that these differences do not impact the TNCO yields between the new and grandfathered tobacco products. Thus, the differences in characteristics between the new and the grandfathered product do not cause the new product to raise different questions of public health.

SE0014675

- 13% increase in (b) (4) in the cigarette paper
- 49% decrease in glue seam/filter total weight
- 75% decrease in (b) (4)
- 29% decrease in tipping glue
- 100% increase in base paper porosity
- 11% decrease in total denier

The differences in characteristics between SE0014675 and the grandfathered product subject of SE0003200, except for glue seam/filter total weight (due to an increase in (b) (4)), and tipping glue total weight, are smaller in magnitude to the changes in these characteristics between the previously found SE product (SE0003200) and the predicate product. However, these changes may have an influence on TNCO smoke yields when comparing the new product to that of the grandfathered product. The applicant provided TNCO yields between the new and grandfathered product which showed a reduction in TNCO yields which demonstrated that these differences do not impact the TNCO yields between the new and grandfathered tobacco products. Thus, the differences in characteristics between the new and the grandfathered product do not cause the new product to 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 SE0014666, SE0014667, SE0014674, and SE0014675.