Technical Project Lead (TPL) Review: SE0014881

SE0014881: Top Premier Menthol 100MM	
Package Type	Box
Package Quantity	200 Tubes
Length	100 mm
Diameter	8.2 mm
Ventilation	0%
Characterizing Flavor	Menthol
Attributes of SE Report	
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 Jeannie H. Jeong-im -S
Date: 2019.04.26 13:53:41 -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: 2019.04.29 08:31:44 -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 product:

SE0014881: Top Premier Menthol 100MM	
Product Name	Premier 100MM Menthol
Package Type	Box
Portion Count	200 Tubes
Length	99 mm
Diameter	8.2 mm
Ventilation	0%
Characterizing Flavor	Menthol

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received one SE report on October 5, 2018, and subsequently issued an Acknowledgement letter on October 10, 2018. FDA issued an Advice/Information request letter on November 30, 2018. The applicant submitted an amendment (SE0015075) which FDA received on January 31, 2019.

Product Name	SE Report	Amendment
Top Premier Menthol 100MM	SE0014881	SE0014911 SE0015075

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for this SE Report.

2. REGULATORY REVIEW

A regulatory review was completed by Nicholas Hasbrouck on October 10, 2018.

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 in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated November 7, 2018, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and, therefore, is an eligible predicate tobacco product.

OCE also completed a review 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 review dated April 26, 2019, concludes that the new tobacco product is 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 Jikun Liu on November 13, 2018 and March 8, 2019.

The final chemistry review concludes that the new tobacco product 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:

- Tipping paper:
  - (b) (4)
  - (b) (4)
- Seam/filter adhesive:
  - Deletion of (b) (4).
  - Addition of (b) (4)
- Acetate tow:
  - Decrease in (b) (4)
- Triacetin:
  - Decrease in (b) (4)
- Tipping glue:
  - Addition of (b) (4)
  - Deletion of (b) (4)
  - Decrease in (b) (4)

The applicant provided detailed information about the tobacco filler ingredients, including the tobacco blend and ingredients added to the tobacco filler used in the RYO test cigarettes, and structural material ingredients in the new and predicate tobacco products. Identical tobacco filler was used in the preparation of the new and predicate RYO cigarettes, which does not raise different questions of public health. TNCO under the CI smoking regimen was provided as well as B[a]P and formaldehyde under both ISO and CI smoking regimens. All analytical methods are

validated. TNCO, B[a]P, and formaldehyde remained the same or decreased for the new product compared to the predicate product. Significant differences in the ingredients of tipping paper, seam/filter adhesive, acetate tow, (b) (4), and tipping glue were identified for the new and predicate products. However, these structural materials are in cigarette filter and not combusted during normal cigarette use. Also, there are changes in the filter (i.e., total denier, density, and tube mass) that may affect tar, nicotine, and B[a]P. As stated above, tar, nicotine, and B[a]P remained the same or decreased for the new product. Therefore, from a chemistry perspective, the differences in characteristics between the new and predicate products do not cause the new product to raise different questions of public health.

4.2. ENGINEERING

Engineering reviews were completed by Pritesh Darji on November 21, 2018, and by Drew Katherine on March 12, 2019.

The final engineering review concludes that the new tobacco product has different characteristics related to product engineering 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:

- 1% increase in filtered tube length.
- 10% decrease in tipping paper length
- 7% decrease in filtered tube mass
- 10% decrease in total denier
- 12% decrease in filter density
- 43% increase in filter pressure drop

For the SE Report, filtered tube length increases (↑1%) and filter pressure drop increases (↑43%). An increase in filter length and pressure drop may result in increased filter efficiency, and in turn, a decrease in tar, nicotine, and B[a]P yields. Tipping paper length decreases (↓10%), while the filter length is identical between the new and predicate products. A decrease in tipping paper length reduces tipping paper overlap, which would increase total air porosity of the tobacco rod. An increase in total air porosity of the tobacco rod may increase air flow and ventilation and decrease TNCO yields. As such, these differences do not cause the new product to raise different questions of public health from an engineering perspective.

The filtered tube mass decreases (↓7%), total denier decreases (↓10%), and filter density decreases (↓12%) in the new tobacco product compared to the predicate tobacco product. A decrease in filtered tube mass with a constant filtered tube length and diameter may be attributed to a decrease in total denier. A decrease in total denier and filter density with a constant denier per filament may result in a decrease in the number of filaments in the filter. This in turn could result in a decrease in the contact between the smoke and filter tow. Thereby, the filter efficiency would decrease and tar, nicotine, and B[a]P yields would increase. The decrease in filtered tube mass, total denier and filter density are deferred to chemistry for evaluation of the yield of tar, nicotine, and B[a]P for the new and predicate products. Therefore, the differences in characteristics between the new and predicate tobacco product do not cause

the new tobacco product to raise different questions of public health from and engineering perspective.

4.3. TOXICOLOGY

A toxicology review was completed by Yanling Chen on March 18, 2019.

The toxicology review identified differences in design parameters between the new and predicate tobacco products, which are discussed further in the engineering section. There are no other identified differences in characteristics between the new and predicate tobacco products. TNCO, B[a]P, and formaldehyde remained the same or decreased for the new product compared to the predicate product. Therefore, the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health related to product toxicology.

5. ENVIRONMENTAL DECISION

Environmental science reviews were completed by Ronald Edwards on November 1, 2018 and February 7, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 17, 2019. The FONSI was supported by an environmental assessment prepared by FDA on April 17, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Tipping paper:
  - (b) (4)
  - addition of (b) (4)
  - 10% decrease in length
- Tipping glue:
  - addition of (b) (4)
  - deletion of (b) (4)
  - decrease in
- Seam/filter adhesive:
  - deletion of (b) (4) and (b) (4)
  - addition of (b) (4)
- Filter:
  - decrease in (12%) in the acetate tow
  - decrease in (8%)
  - 10% decrease in total denier
  - 12% decrease in filter density
  - 43% increase in filter pressure drop
- Overall
  - 1% increase in filtered tube length

- 7% decrease in filtered tube mass

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. The new tobacco product has differences in tipping paper, filter, and adhesives. The differences occur in the non-combusted components and are not expected to volatize under the intended conditions of use. A decrease in total denier and filter density combined with a constant denier per filament may result in a decrease in the number of filaments in the filter. This could result in a decrease in the contact between the smoke and filter tow; thereby decreasing filter efficiency and increasing the tar, nicotine, and B[a]P yields. However, the applicant provided TNCO, B[a]P, and formaldehyde and they have all remained the same or decreased. Therefore, the differences in characteristics between the new and predicate products do not cause the new tobacco product 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).

The new tobacco product is currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude that the differences between the new and predicate tobacco products are such that the new tobacco product does not raise different questions of public health. I concur with these reviews and recommend that an SE order letter be issued.

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 SE0014881, as identified on the cover page of this review.