FDA U.S. FOOD & DRUG ADMINISTRATION

# Technical Project Lead (TPL) Review: SE0015610, SE0015611 and SE0015631

| SE0015610: Top Premier Menthol 100MM (injector tubes) | |
|---|---|
| Package Type | Box |
| Package Quantity | 200 tubes |
| Length | 100 mm |
| Diameter | 8.2 mm |
| Ventilation | None |
| Characterizing Flavor | Menthol |
| **SE0015611: Top Menthol 100MM (injector tubes)** | |
| Package Type | Box |
| Package Quantity | 250 tubes |
| Length | 100 mm |
| Diameter | 8.2mm |
| Ventilation | None |
| Characterizing Flavor | Menthol |
| **SE0015631: Top Menthol King Size (injector tubes)** | |
| Package Type | Box |
| Package Quantity | 250 tubes |
| Length | 84 mm |
| Diameter | 8.2 mm |
| Ventilation | None |
| Characterizing Flavor | Menthol |
| **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 Gloria J. Kulesa -S
Date: 2020.03.12 12:22:50 -04'00'

Gloria Kulesa
Engineering 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: 2020.03.12 13:11:51 -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:

| SE0015610: Top Premier Menthol 100MM (injector tubes) | |
|---|---|
| **Product Name** | Top Premier Menthol 100MM |
| **Package Type** | Box |
| **Package Quantity** | 200 tubes |
| **Length** | 100 mm |
| **Diameter** | 8.2 mm |
| **Ventilation** | None |
| **Characterizing Flavor** | Menthol |
| **SE0015611: Top Menthol 100MM (injector tubes)** | |
| **Product Name** | Top Premier Menthol 100MM |
| **Package Type** | Box |
| **Package Quantity** | 200 tubes |
| **Length** | 100 mm |
| **Diameter** | 8.2 mm |
| **Ventilation** | None |
| **Characterizing Flavor** | Menthol |
| **SE0015631: Top Menthol King Size (injector tubes)** | |
| **Product Name** | Top McClintock Menthol King Size |
| **Package Type** | Box |
| **Package Quantity** | 200 tubes |
| **Length** | 84 mm |
| **Diameter** | 8.2 mm |
| **Ventilation** | None |
| **Characterizing Flavor** | Menthol |

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 December 17, 2019, FDA received two SE Reports (SE0015610-SE0015611) from Republic Tobacco, LP and subsequently issued an acknowledgement letter on December 20, 2019. On December 20, 2019, FDA received one SE Report (SE0015631) from Republic Tobacco, LP and subsequently issued an acknowledgement letter on December 23, 2019.

| Product Name | SE Report | Amendments |
|---|---|---|
| Top Premier Menthol 100MM | SE0015610 | N/A |
| Top Menthol 100MM | SE0015611 | |
| Top Menthol King Size | SE0015631 | |

### 1.3. SCOPE OF REVIEW

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

## 2. REGULATORY REVIEW

Acceptance reviews were completed by Donna Cheung on December 20, 2019 (SE0015610-SE0015611), and December 23, 2019 (SE0015631). The reviews conclude that the SE Reports are administratively complete.

## 3. COMPLIANCE REVIEW

The predicate tobacco products in SE0015610, SE0015611 and SE0015631 were previously 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 |
|---|---|---|---|
| SE0015610 | Top Premier Menthol 100MM | SE0014881 | April 29, 2019 |
| SE0015611 | | | |
| SE0015631 | Top McClintock Menthol King Size | SE0014667 | April 16, 2019 |

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 February 27, 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

A chemistry review was completed by Abdur-Rafay Shareef on February 7, 2020.

The 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:

- 2% lower quantity of tipping paper (b) (4) mg/product versus (b) (4) mg/product for SE0015610 and SE0015611; (b) (4) mg/product versus (b) (4) mg/product for SE0015631).
- Individual ingredients that comprise the tipping paper in the new and corresponding predicate tobacco products were different.

For all SE Reports, the applicant has submitted harmful and potentially harmful constituents (HPHC) yields that indicated the new and corresponding predicate tobacco products are analytically equivalent, and thus no additional information is needed from a chemistry perspective. Also, tipping paper is not combusted. 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 Michael Morschauser on January 29, 2020.

The engineering review did not identify any differences in characteristics between the new and corresponding predicate tobacco products 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.

## 4.3. TOXICOLOGY

A toxicology review was completed by Ana Depina on February 7, 2020.

The toxicology review concludes that the new tobacco products have different characteristics related to toxicology 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:

- Changes in tipping paper ingredients including the binder, plasticizer, processing aid, sizing agent, and colors.
- For SE0015610 and SE0015611, the measured tar, nicotine, and carbon monoxide (TNCO) data provided indicate a minimal increase in CO (2%) that is analytically equivalent, and all other HPHCs are decreased or unchanged.
- For SE0015631, the data provided indicate minimal increases for all measured HPHCs (1-3%), except for tar, which decreased in the new tobacco product as compared to the predicate tobacco product.

Tipping paper is not combusted, volatized or released during cigarette consumption. Consumer exposure to the tipping paper ingredients while smoking, is expected to be

minimal. Thus, changes in the tipping paper ingredients are not likely to cause the new tobacco products to raise different questions of public health from a toxicological perspective. The applicant submitted TNCO data for the new and predicate tobacco products using an identical RYO tobacco blend. All minimal increases were determined to be analytically equivalent. All other HPHCs decreased or remained unchanged. The TNCO data support that any differences in characteristics between the new and predicate tobacco products 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 toxicology perspective.

## 5. ENVIRONMENTAL DECISION

An environmental review was completed by Dilip Venugopal on January 29, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on February 6, 2020. The FONSI was supported by an environmental assessment prepared by FDA on February 6, 2020.

## 6. CONCLUSION AND RECOMMENDATION

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

- 2% decrease in tipping paper
- Tipping paper ingredient differences in the binder, plasticizer, processing aid, sizing agent, and colors
- 2% increase in CO (for SE0015610 and SE0015611); remaining HPHCs decreased
- 1-3% increase in HPHCs (for SE0015631), except for tar, which decreased

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. Tipping paper is not combusted, therefore, the small decrease in the tipping paper and the differences in its ingredients does not cause the new tobacco product to raise different questions of public health. The applicant submitted TNCO data for the new and predicate tobacco products. The 2% increase in CO for SE0015610 and SE0015611 was determined to be analytically equivalent and all of the remaining HPHCs decreased or were unchanged in the new tobacco products in comparison to the corresponding predicate tobacco products. Therefore, the change in the HPHCs does not cause the new tobacco products to raise different questions of public health for SE0015610 and SE0015611. For SE0015631, there was a 1-3% increase in all HPHCs, except for tar, which decreased in the comparison between the new and predicate tobacco products. All minimal increases in HPHCs were determined to be analytically equivalent. Therefore, the change in the HPHCs does not cause the new tobacco product to raise different question of public health for SE0015631. 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.

The predicate tobacco products were previously determined to be substantially equivalent by FDA under SE0014881 and SE0014667.

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 SE0015610, SE0015611 and SE0015631 were previously determined to be substantially equivalent by FDA under SE0014881 and SE0014667, respectively. Comparison of the new tobacco products to the grandfathered tobacco products (Premier 100MM Menthol in SE0014881 and Top Menthol King Size in SE0014667) reveals that the new tobacco products have the following differences in characteristics from Premier 100MM Menthol and Top Menthol King Size, the grandfathered tobacco products:

SE0015610 & SE0015611

- Decrease in filter total denier (10%)
- Decrease in filter density (12%)
- Decrease in filter pressure drop (43%)
- Decrease in tipping paper length (10%)
- Increase in tipping paper total weight (86%)

SE0015631

- Decrease in total denier (6%)
- Decrease in filter denier per filament (14%)
- Increase in filter density (26%)
- Decrease in tipping paper total weight (3%)

The differences in characteristics listed above between the new and grandfathered tobacco products in SE0014881 are decreased in magnitude except for the increased tipping paper total weight. A decrease in filter total denier and filter density may result in a decrease in the number of filaments in the filter. This may result in a decrease in the contact between the smoke and filter tow, thereby decrease filter efficiency and increase the tar and nicotine yields. A decrease in the filter pressure drop may decrease filter efficiency and thereby increase tar and nicotine. However, the applicant provided TNCO data which showed results that were analytically equivalent or decreasing. Tipping paper is not combusted, therefore the increase in the tipping paper does not cause the new tobacco product to raise different questions of public health. The differences in characteristics listed above between the new and grandfathered tobacco products in SE0014667 are all decreases in magnitude, except for an increase in filter density. A decrease in total denier may result in increased tar and nicotine, while a decrease in denier per filament and an increase in filter density may result in decreased tar and nicotine. The smaller change in filter total denier is likely to be balanced out by the larger percent changes in filter denier per filament and filter density. This was confirmed by the analysis of the TNCO and HPHC measurements. Therefore, these differences do not cause the new product to raise different questions of public health. In summary, the differences do not cause the new tobacco products in SE0015610, SE0015611 and SE0015631 to raise different questions of public health. Therefore, whether comparing the new tobacco products in SE0015610, SE0015611 and SE0015631 to the predicate or 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 SE0015610, SE0015611 and SE0015631, as identified on the cover page of this review.