Technical Project Lead (TPL) Review: SE0015715-SE0015718 and SE0015720-SE0015723

<table>
<thead>
<tr>
<th>SE0015715: Chesterfield Blue Pack 100's Box</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Package Type</td>
<td>Hard Pack</td>
</tr>
<tr>
<td>Package Quantity</td>
<td>20 Cigarettes</td>
</tr>
<tr>
<td>Length</td>
<td>98.5 mm</td>
</tr>
<tr>
<td>Diameter&lt;sup&gt;1&lt;/sup&gt;</td>
<td>7.89 mm</td>
</tr>
<tr>
<td>Ventilation</td>
<td>20%</td>
</tr>
<tr>
<td>Characterizing Flavor</td>
<td>None</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SE0015716: Chesterfield Menthol Box</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Package Type</td>
<td>Hard Pack</td>
</tr>
<tr>
<td>Package Quantity</td>
<td>20 Cigarettes</td>
</tr>
<tr>
<td>Length</td>
<td>83.0 mm</td>
</tr>
<tr>
<td>Diameter&lt;sup&gt;1&lt;/sup&gt;</td>
<td>7.89 mm</td>
</tr>
<tr>
<td>Ventilation</td>
<td>0%</td>
</tr>
<tr>
<td>Characterizing Flavor</td>
<td>Menthol</td>
</tr>
<tr>
<td>Additional Property</td>
<td>Tipping Paper 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SE0015717: Chesterfield Box</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Package Type</td>
<td>Hard Pack</td>
</tr>
<tr>
<td>Package Quantity</td>
<td>20 cigarettes</td>
</tr>
<tr>
<td>Length</td>
<td>83.0 mm</td>
</tr>
<tr>
<td>Diameter&lt;sup&gt;1&lt;/sup&gt;</td>
<td>7.89 mm</td>
</tr>
<tr>
<td>Ventilation</td>
<td>0%</td>
</tr>
<tr>
<td>Characterizing Flavor</td>
<td>None</td>
</tr>
<tr>
<td>Additional Property</td>
<td>Tipping Paper 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SE0015718: Marlboro Menthol Smooth Ice Box</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Package Type</td>
<td>Hard Pack</td>
</tr>
<tr>
<td>Package Quantity</td>
<td>20 cigarettes</td>
</tr>
<tr>
<td>Length</td>
<td>83.0 mm</td>
</tr>
<tr>
<td>Diameter&lt;sup&gt;1&lt;/sup&gt;</td>
<td>7.89 mm</td>
</tr>
<tr>
<td>Ventilation</td>
<td>34%</td>
</tr>
<tr>
<td>Characterizing Flavor</td>
<td>Menthol</td>
</tr>
</tbody>
</table>

<sup>1</sup> The applicant submitted the circumference which allowed for a calculation of diameter.
<table>
<thead>
<tr>
<th>Model</th>
<th>Description</th>
<th>Package Type</th>
<th>Package Quantity</th>
<th>Length (mm)</th>
<th>Diameter (1) (mm)</th>
<th>Ventilation %</th>
<th>Characterizing Flavor</th>
<th>Additional Property</th>
</tr>
</thead>
<tbody>
<tr>
<td>SE0015720</td>
<td>Chesterfield Box</td>
<td>Hard Pack</td>
<td>20 cigarettes</td>
<td>83.0</td>
<td>7.89</td>
<td>0</td>
<td>None</td>
<td>Tipping Paper 2</td>
</tr>
<tr>
<td>SE0015721</td>
<td>Chesterfield Box</td>
<td>Hard Pack</td>
<td>20 cigarettes</td>
<td>83</td>
<td>7.89</td>
<td>0</td>
<td>None</td>
<td>Tipping Paper 3</td>
</tr>
<tr>
<td>SE0015722</td>
<td>Chesterfield Menthol Box</td>
<td>Hard Pack</td>
<td>20 cigarettes</td>
<td>83</td>
<td>7.89</td>
<td>0</td>
<td>Menthol</td>
<td>Tipping Paper 2</td>
</tr>
<tr>
<td>SE0015723</td>
<td>Chesterfield Menthol Box</td>
<td>Hard Pack</td>
<td>20 cigarettes</td>
<td>83.0</td>
<td>7.89</td>
<td>0</td>
<td>Menthol</td>
<td>Tipping Paper 3</td>
</tr>
</tbody>
</table>

**Attributes of SE Reports**

- **Applicant**: Philip Morris USA Inc.
- **Report Type**: Regular
- **Product Category**: Cigarette
- **Product Sub-Category**: Combusted, Filtered

**Recommendation**

Issue Substantially Equivalent (SE) orders.
TPL Review for SE0015715-SE0015718 and SE0015720-SE0015723

Technical Project Lead (TPL):

Digitally signed by Charles Feng -S
Date: 2020.05.20 11:43:24 -04'00'

Charles Feng, 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: 2020.05.20 12:06:10 -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:

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Package Type</th>
<th>Package Quantity</th>
<th>Length</th>
<th>Diameter</th>
<th>Ventilation</th>
<th>Characterizing Flavor</th>
<th>Additional Property</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SE0015715: Chesterfield Blue Pack 100's Box</strong></td>
<td>Hard Pack</td>
<td>20 Cigarettes</td>
<td>98.5 mm</td>
<td>7.89 mm</td>
<td>20%</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td><strong>SE0015716: Chesterfield Menthol Box</strong></td>
<td>Hard Pack</td>
<td>20 Cigarettes</td>
<td>83.0 mm</td>
<td>7.89 mm</td>
<td>0%</td>
<td>Menthol</td>
<td>Tipping Paper 1</td>
</tr>
<tr>
<td><strong>SE0015717: Chesterfield Box</strong></td>
<td>Hard Pack</td>
<td>20 Cigarettes</td>
<td>83.0 mm</td>
<td>7.89 mm</td>
<td>0%</td>
<td>None</td>
<td>Tipping Paper 1</td>
</tr>
<tr>
<td>Product Name</td>
<td>Marlboro Menthol Smooth Ice Box</td>
<td>Chesterfield Box</td>
<td>Chesterfield Box</td>
<td>Chesterfield Menthol Box</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------------------</td>
<td>---------------------------------</td>
<td>------------------</td>
<td>------------------</td>
<td>--------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Package Type</td>
<td>Hard Pack</td>
<td>Hard Pack</td>
<td>Hard Pack</td>
<td>Hard Pack</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Package Quantity</td>
<td>20 Cigarettes</td>
<td>20 Cigarettes</td>
<td>20 Cigarettes</td>
<td>20 Cigarettes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length</td>
<td>83.0 mm</td>
<td>83.0 mm</td>
<td>83.0 mm</td>
<td>83.0 mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diameter</td>
<td>7.89 mm</td>
<td>7.89 mm</td>
<td>7.89 mm</td>
<td>7.89 mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ventilation</td>
<td>34%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Characterizing Flavor</td>
<td>Menthol</td>
<td>None</td>
<td>None</td>
<td>Menthol</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Properties</td>
<td></td>
<td>Tipping Paper 2</td>
<td>Tipping Paper 3</td>
<td>Tipping Paper 2</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The predicate tobacco products are combusted, filtered cigarettes manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On February 20, 2020, FDA received eight SE Reports from Altria Client Services LLC, on behalf of Philip Morris USA Inc. FDA issued an Acceptance letter to the applicant on February 27, 2020.

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 Jessica Kiser on February 27, 2020.

The reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco products in SE0015715-SE0015718 and SE0015720-SE0015723 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.

<table>
<thead>
<tr>
<th>SE Report</th>
<th>Predicate Tobacco Product</th>
<th>Predicate Tobacco Product Found SE Under:</th>
<th>SE Order Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>SE0015715</td>
<td>Chesterfield Blue Pack 100's Box</td>
<td>SE0015058</td>
<td>April 8, 2019</td>
</tr>
<tr>
<td>SE0015716</td>
<td>Chesterfield Menthol Box</td>
<td>SE0014891</td>
<td>January 15, 2019</td>
</tr>
<tr>
<td>SE0015717</td>
<td>Chesterfield Box</td>
<td>SE0014892</td>
<td>January 15, 2019</td>
</tr>
<tr>
<td>SE0015718</td>
<td>Marlboro Menthol Gold Pack Box</td>
<td>SE0014203</td>
<td>March 1, 2018</td>
</tr>
<tr>
<td>SE0015720</td>
<td>Chesterfield Box</td>
<td>SE0014907</td>
<td>January 15, 2019</td>
</tr>
<tr>
<td>SE0015721</td>
<td>Chesterfield Box</td>
<td>SE0014815</td>
<td>September 27, 2018</td>
</tr>
</tbody>
</table>
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 April 9, 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 Rachel Lerebours on April 8, 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:

- **Cigarette Seam Adhesive**
  - Addition of [mg/cig]
  - Addition of [mg/cig]
  - Addition of [mg/cig]
  - Decrease in (~47-48%)
  - Increase in [content (↑13%)]

- **Tipping Adhesive**
  - Addition of [mg/cig]

- **Monogram ink (SE0015717, SE0015720 and SE0015721)**
  - Removal of [mg/cig]
  - Decrease in (~13%)
  - Increase in (~17%)
  - Decrease in (~17%)

The applicant provided certification statements for all SE Reports, certifying that the new and corresponding predicate tobacco products have identical characteristics except for minor differences in the cigarette seam adhesive (all SE Reports), tipping adhesive (all SE Reports) and monogram ink (SE0015717, SE0015720, SE0015721). From a chemistry perspective, the only change in these components that may affect mainstream smoke yields is the addition of [mg/cig] that could increase carbonyls, such as acrolein, formaldehyde, acetaldehyde. Although the new tobacco products contain substantial relative percent increase in (~13%), the absolute increase in (~47-48%) is small (~mg/cig) and during the storage of the new and corresponding predicate tobacco products, (~17%) is expected to evaporate or equilibrate with the environment, and therefore, is not expected to change the smoke chemistry. The applicant provided mainstream smoke yields for harmful and potentially harmful constituents (HPHCs) including carbonyls measured under ISO and Cl smoking.
regimens for all the new and predicate tobacco products. A comparison using the two one-sided t-test (TOST) indicated that all mainstream smoke yields between the new and corresponding predicate tobacco products were analytically equivalent. Overall, the differences in the cigarette seam adhesive, tipping adhesive, and monogram ink between the new tobacco products are not expected to impact HPHCs yields from a chemistry 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 from a chemistry perspective.

4.2. TOXICOLOGY

A toxicology review was completed by Jueichuan Kang on April 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:

- Cigarette seam adhesive
  - (added)
  - 2

- Tipping adhesive
  - 1
  - 3

For all SE Reports, there are changes in the cigarette seam adhesive in the burned portion of
the new tobacco products, compared to their corresponding predicate tobacco products. These changes include additions of \( \text{mg/cig} \), \( \text{mg/cig} \), and addition of a complex ingredient \( \text{mg/cig} \), consisted of 14 individual ingredients. In addition, \( \text{mg/cig} \) is added to the tipping adhesive in all SE Reports. Collectively, the added ingredients in the cigarette seam adhesive can pyrolyze to form HPHCs including CO, benzene, toluene, 1,3-butadiene, acetaldehyde, acrolein, and formaldehyde. The applicant provided data for the aforementioned HPHCs in mainstream smoke under ISO and CI regimens in four representative SE Reports, and these HPHC levels are analytically equivalent between the new and corresponding predicate tobacco products by a TOST analysis. Therefore, the additions of new ingredients in the cigarettes seam adhesive are not expected to cause the new tobacco products to raise different questions of public health from a toxicological perspective. In addition, \( \text{mg/cig} \) is added to the tipping adhesive. Tipping adhesive is not expected to be burned or be a potential source of thermal degradation leading to the generation of HPHCs. Smokers are not expected to have direct oral or dermal contact with any residual \( \text{mg/cig} \) in the tipping adhesive as the glue is bound at the tipping paper seam which is covered by the tipping paper. Therefore, in all SE Reports, the addition of \( \text{mg/cig} \) to the tipping adhesive of the new tobacco products is unlikely to cause the new tobacco products to raise different questions of public health from a toxicological 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 from a toxicological perspective.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Rudaina Alrefai-Kirkpatrick on March 30, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 15, 2020. The FONSI was supported by an environmental assessment prepared by FDA on April 15, 2020.

6. CONCLUSION AND RECOMMENDATION

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

- Cigarette Seam Adhesive
  - Addition of \( \text{mg/cig} \)
  - Addition of \( \text{mg/cig} \)
  - Decrease in (\( \downarrow 47 - 48\% \))
  - Increase in content (\( \uparrow 367 - 379\% \))
  - Addition of \( \text{mg/cig} \)
  - \( \text{ng/cig} \)
  - \( \text{ng/cig} \)
  - \( \text{ng/cig} \)
The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. There are changes in the cigarette seam adhesive in the burned portion of the new tobacco products, compared to their corresponding predicate tobacco products. These changes include additions of \((b) (4)\), and addition of a complex ingredient, \((b) (4)\). Collectively, the added ingredients in the cigarette seam adhesive can pyrolyze to form HPHCs including CO, benzene, toluene, 1,3-butadiene, acetaldehyde, acrolein, and formaldehyde. The applicant provided data for these HPHCs under ISO and CI regimens, which are analytically equivalent between the new and corresponding predicate tobacco products by a TOST analysis. Therefore, the additions of new ingredients in the cigarettes seam adhesive are not expected to cause the new tobacco products to raise different questions. In addition, \(\text{Tipping Adhesive}\) is added to the tipping adhesive. Tipping adhesive is not expected to be burned or be a potential source of thermal degradation leading to the generation of HPHCs. Smokers are not expected to have direct oral or dermal contact with any residual \(\text{Tipping Adhesive}\) in the tipping adhesive as the \((b) (4)\) is bound at the tipping paper seam which is covered by the tipping paper. Therefore, the addition of \((b) (4)\) to the tipping adhesive of the new tobacco products does not cause any concerns from a toxicological perspective. Furthermore, the decreases in monogram ink ingredients and \(\text{Monogram ink (SE0015717, SE0015720 and SE0015721)}\) are not expected to increase HPHC yields. 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 SE0015058, SE0014891, SE0014892, SE0014203, SE0014907, SE0014815, SE0014906 and SE0014816.
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 SE0015715, SE0015716, SE0015717, SE0015718, SE0015720, SE0015721, SE0015722 and SE0015723 were previously determined to be substantially equivalent by FDA under SE0015058, SE0014891, SE0014892, SE0014203, SE0014907, SE0014815, SE0014906 and SE0014816, respectively. Comparison of the new tobacco products to the grandfathered tobacco products (Basic Lights 100s Box in SE0015058, Basic Menthol Box in SE0014891, Basic Full Flavor Box in SE0014892, Marlboro Lights Menthol Box in SE0014203, Basic Full Flavor Box in SE0014907, Basic Full Flavor Box in SE0014815, Basic Menthol Box in SE0014906, and Basic Menthol Box in SE0014816) reveals that the new tobacco products have the following differences in characteristics from Basic Lights 100s Box, Basic Menthol Box, Basic Full Flavor Box, Marlboro Lights Menthol Box, Basic Full Flavor Box, Basic Full Flavor Box, Basic Menthol Box, and Basic Menthol Box, the grandfathered tobacco products:

**Cigarette Seam adhesive**
- All SE Reports
  - Addition of \( (\downarrow \text{mg/cig}) \)
  - Addition of \( (\downarrow \text{mg/cig}) \)
  - Addition of \( (\downarrow \text{mg/cig}) \)
  - Decrease in \( (\downarrow 47-48\%) \)
  - Increase in content \( (\uparrow 367-379\%) \)

**Tipping Adhesive**
- All SE Reports
  - Addition of \( (\downarrow \text{mg/cig}) \)

**Monogram Ink**
- For SE0015717, SE0015720 and SE0015721
  - Removal of \( (\downarrow \text{mg/cig}) \)
  - Decrease in \( (\downarrow 13\%) \)
  - Decrease in \( (\downarrow 17\%) \)
  - Increase in \( (\downarrow 17\%) \)

**Base Tipping Paper**
- For SE0015715
  - Addition of \( (\downarrow \text{mg/cig}, \uparrow \text{mg/cig}) \)
  - Removal of \( (\downarrow \text{mg/cig}, \downarrow \text{mg/cig}) \)
  - Decrease in \( (\downarrow \text{mg/cig}, \downarrow 64\%) \)
  - Increase in \( (\downarrow \text{mg/cig}, \uparrow 211\%) \)
- For SE0015716 and SE0015717
  - Addition of \( (\downarrow \text{mg/cig}) \)
  - Addition of \( (\downarrow \text{mg/cig}) \)
  - Addition of \( (\downarrow \text{mg/cig}) \)
Addition of mg/cig)
• Removal of mg/cig)

• For SE0015720 and SE0015722
  o Increase in mg/cig, ↑64%
  o Addition of mg/cig)
  o Increase in mg/cig, ↑1627%
  o Addition of mg/cig)
  o Decrease in (↓41%)

• For SE0015721 and SE0015723
  o Addition of ...
  o Removal of ...
  o Decrease in (↓90%)

Ingredients added to tobacco
• For SE0015718
  o Removal of mg/cig)

The differences in characteristics listed above, other than the differences in cigarette seam adhesive, tipping adhesive, and monogram ink, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0015058, SE0014891, SE0014892, SE0014203, SE0014907, SE0014815, SE0014906 and SE0014816. Therefore, these differences do not cause the new tobacco products in SE0015715-SE0015718 and SE0015720-SE0015723 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in cigarette seam adhesive, tipping adhesive, and monogram ink between the new tobacco products in SE0015715-SE0015718 and SE0015720-SE0015723 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 SE0015715-SE0015718 and SE0015720-SE0015723 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 SE0015715-SE0015718 and SE0015720-SE0015723, as identified on the cover page of this review.