

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

<b>SE0015715: Chesterfield Blue Pack 100's Box</b>	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter <sup>1</sup>	7.89 mm
Ventilation	20%
Characterizing Flavor	None
<b>SE0015716: Chesterfield Menthol Box</b>	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83.0 mm
Diameter <sup>1</sup>	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 1
<b>SE0015717: Chesterfield Box</b>	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83.0 mm
Diameter <sup>1</sup>	7.89 mm
Ventilation	0%
Characterizing Flavor	None
Additional Property	Tipping Paper 1
<b>SE0015718: Marlboro Menthol Smooth Ice Box</b>	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83.0 mm
Diameter <sup>1</sup>	7.89 mm
Ventilation	34%
Characterizing Flavor	Menthol

<sup>1</sup> The applicant submitted the circumference which allowed for a calculation of diameter.

<b>SE0015720: Chesterfield Box</b>	
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	83.0 mm
<b>Diameter<sup>1</sup></b>	7.89 mm
<b>Ventilation</b>	0%
<b>Characterizing Flavor</b>	None
<b>Additional Property</b>	Tipping Paper 2
<b>SE0015721: Chesterfield Box</b>	
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	83 mm
<b>Diameter<sup>1</sup></b>	7.89 mm
<b>Ventilation</b>	0%
<b>Characterizing Flavor</b>	None
<b>Additional Property</b>	Tipping Paper 3
<b>SE0015722: Chesterfield Menthol Box</b>	
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	83 mm
<b>Diameter<sup>1</sup></b>	7.89 mm
<b>Ventilation</b>	0%
<b>Characterizing Flavor</b>	Menthol
<b>Additional Property</b>	Tipping Paper 2
<b>SE0015723: Chesterfield Menthol Box</b>	
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	83.0 mm
<b>Diameter<sup>1</sup></b>	7.89 mm
<b>Ventilation</b>	0%
<b>Characterizing Flavor</b>	Menthol
<b>Additional Property</b>	Tipping Paper 3
<b>Attributes of SE Reports</b>	
<b>Applicant</b>	Philip Morris USA Inc.
<b>Report Type</b>	Regular
<b>Product Category</b>	Cigarette
<b>Product Sub-Category</b>	Combusted, Filtered
<b>Recommendation</b>	
Issue Substantially Equivalent (SE) orders.	

**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:

<b>SE0015715: Chesterfield Blue Pack 100's Box</b>	
<b>Product Name</b>	Chesterfield Blue Pack 100's Box
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Length</b>	98.5 mm
<b>Diameter<sup>1</sup></b>	7.89 mm
<b>Ventilation</b>	20%
<b>Characterizing Flavor</b>	None
<b>SE0015716: Chesterfield Menthol Box</b>	
<b>Product Name</b>	Chesterfield Menthol Box
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Length</b>	83.0 mm
<b>Diameter<sup>1</sup></b>	7.89 mm
<b>Ventilation</b>	0%
<b>Characterizing Flavor</b>	Menthol
<b>Additional Property</b>	Tipping Paper 1
<b>SE0015717: Chesterfield Box</b>	
<b>Product Name</b>	Chesterfield Box
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Length</b>	83.0 mm
<b>Diameter<sup>1</sup></b>	7.89 mm
<b>Ventilation</b>	0%
<b>Characterizing Flavor</b>	None
<b>Additional Property</b>	Tipping Paper 1

<b>SE0015718: Marlboro Menthol Smooth Ice Box</b>	
<b>Product Name</b>	Marlboro Menthol Gold Pack Box
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Length</b>	83.0 mm
<b>Diameter<sup>1</sup></b>	7.89 mm
<b>Ventilation</b>	34%
<b>Characterizing Flavor</b>	Menthol
<b>SE0015720: Chesterfield Box</b>	
<b>Product Name</b>	Chesterfield Box
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Length</b>	83.0 mm
<b>Diameter<sup>1</sup></b>	7.89 mm
<b>Ventilation</b>	0%
<b>Characterizing Flavor</b>	None
<b>Additional Properties</b>	Tipping Paper 2
<b>SE0015721: Chesterfield Box</b>	
<b>Product Name</b>	Chesterfield Box
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Length</b>	83.0 mm
<b>Diameter<sup>1</sup></b>	7.89 mm
<b>Ventilation</b>	0%
<b>Characterizing Flavor</b>	None
<b>Additional Property</b>	Tipping Paper 3
<b>SE0015722: Chesterfield Menthol Box</b>	
<b>Product Name</b>	Chesterfield Menthol Box
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Length</b>	83.0 mm
<b>Diameter<sup>1</sup></b>	7.89 mm
<b>Ventilation</b>	0%
<b>Characterizing Flavor</b>	Menthol
<b>Additional Property</b>	Tipping Paper 2

SE0015723: Chesterfield Menthol Box	
Product Name	Chesterfield Menthol Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83.0 mm
Diameter <sup>1</sup>	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 3

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.

SE Report	Predicate Tobacco Product	Predicate Tobacco Product Found SE Under:	SE Order Date
SE0015715	Chesterfield Blue Pack 100's Box	SE0015058	April 8, 2019
SE0015716	Chesterfield Menthol Box	SE0014891	January 15, 2019
SE0015717	Chesterfield Box	SE0014892	January 15, 2019
SE0015718	Marlboro Menthol Gold Pack Box	SE0014203	March 1, 2018
SE0015720	Chesterfield Box	SE0014907	January 15, 2019
SE0015721	Chesterfield Box	SE0014815	September 27, 2018

SE0015722	Chesterfield Menthol Box	SE0014906	January 15, 2019
SE0015723	Chesterfield Menthol Box	SE0014816	September 27, 2018

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 (b) (4) mg/cig
  - Addition of (b) (4) mg/cig
  - Addition of (b) (4) mg/cig
  - Decrease in (b) (4) (↓47-48%)
  - Increase in (b) (4) content (↑367-379%)
- Tipping Adhesive
  - Addition of (b) (4) mg/cig
- Monogram ink (SE0015717, SE0015720 and SE0015721)
  - Removal of (b) (4) mg/cig
  - Decrease in (b) (4) (↓13%)
  - Decrease in (b) (4) (↓17%)
  - Decrease in (b) (4) (↓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 (b) (4) mg/cig that could increase carbonyls, such as acrolein, formaldehyde, acetaldehyde. Although the new tobacco products contain substantial relative percent increase in (b) (4) the absolute increase in (b) (4) is small (b) (4) mg/cig and during the storage of the new and corresponding predicate tobacco products, (b) (4) 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 CI smoking





the new tobacco products, compared to their corresponding predicate tobacco products. These changes include additions of (b) (4) mg/cig), (b) (4) mg/cig), and addition of a complex ingredient (b) (4), consisted of 14 individual ingredients. In addition, (b) (4) 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, (b) (4) 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 (b) (4) 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 (b) (4) 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 toxicology 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 (b) (4) mg/cig)
  - Addition of (b) (4) mg/cig)
  - Decrease in (b) (4) (↓47 – 48%)
  - Increase in (b) (4) content (↑367 – 379%)
  - Addition of (b) (4)
    - (b) (4) ng/cig)
    - (b) (4) ng/cig)
    - (b) (4) ng/cig)
    - (b) (4) ng/cig)

- (b) (4) ng/cig)
  - (b) (4) ng/cig)
  - (b) (4) ng/cig)
  - (b) (4) ng/cig)
  - (b) (4) ng/cig)
  - (b) (4) ng/cig)
  - (b) (4) μg/cig)
  - (b) (4) ng/cig)
  - (b) (4) ng/cig)
  - (b) (4) g/cig)
- Tipping Adhesive
    - Addition of (b) (4) mg/cig)
  - Monogram ink (SE0015717, SE0015720 and SE0015721)
    - Removal of (b) (4) mg/cig)
    - Decrease in (b) (4) (↓13%)
    - Decrease in (b) (4) (↓17%)
    - Decrease in (b) (4) (↓17%)

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, (b) (4) 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 (b) (4) 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 (b) (4) 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 (b) (4) mg/cig)
  - Addition of (b) (4) mg/cig)
  - Addition of (b) (4) mg/cig)
  - Decrease in (b) (4) (↓47-48%)
  - Increase in (b) (4) content (↑367-379%)

**Tipping Adhesive**

- All SE Reports
  - Addition of (b) (4) mg/cig)

**Monogram Ink**

- For SE0015717, SE0015720 and SE0015721
  - Removal of (b) (4) mg/cig)
  - Decrease in (b) (4) (↓13%)
  - Decrease in (b) (4) (↓17%)
  - Decrease in (b) (4) (↓17%)

**Base Tipping Paper**

- For SE0015715
  - Addition of (b) (4) mg/cig), (b) (4) mg/cig), (b) (4) /cig), and (b) (4) /cig)
  - Removal of (b) (4) mg/cig) and (b) (4) mg/cig)
  - Decrease in (b) (4) mg/cig, ↓64%)
  - Increase in (b) (4) mg/cig, ↑211%)
- For SE0015716 and SE0015717
  - Addition of (b) (4) cig)
  - Addition of (b) (4) mg/cig)
  - Addition of (b) (4) mg/cig)
  - Addition of (b) (4) mg/cig)

- Addition of (b) (4) mg/cig)
- Removal of (b) (4) mg/cig)
- For SE0015720 and SE0015722
  - Increase in (b) (4) mg/cig, ↑64%)
  - Addition of (b) (4) mg/cig)
  - Increase in (b) (4) mg/cig, ↑1627%)
  - Addition of (b) (4) mg/cig)
  - Decrease in (b) (4) (↓41%)
- For SE0015721 and SE0015723
  - Addition of (b) (4)
  - Removal of (b) (4)
  - Decrease in (b) (4) (↓90%)

**Ingredients added to tobacco**

- For SE0015718
  - Removal of (b) (4) 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.