

**Technical Project Lead (TPL) Review: SE0014891, SE0014892, SE0014906 and SE0014907**

|  |                        |
|--|------------------------|
| <b>SE0014891: 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 1        |
| <b>SE0014892: 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 1        |
| <b>SE0014906: 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>SE0014907: 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 2        |
| <b>Attributes of SE Reports</b>            |                        |
| <b>Applicant</b>                           | Philip Morris USA Inc. |
| <b>Report Type</b>                         | Regular                |

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

|   |                    |
|---|--------------------|
| <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 Shixia Feng -S  
Date: 2019.01.15 09:33:21 -05'00'

Shixia 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)

|                                 |   |
|---------------------------------|---|
| <b>Matthew R.<br/>Holman -S</b> | Digitally signed by Matthew R.<br>Holman -S<br>Date: 2019.01.15 09:49:28<br>-05'00' |
|---------------------------------|---|

Matthew R. Holman, Ph.D.  
Director  
Office of Science

## TABLE OF CONTENTS

|  |          |
|--|----------|
| <b>1. BACKGROUND .....</b>                           | <b>4</b> |
| 1.1. PREDICATE TOBACCO PRODUCTS .....                | 4        |
| 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW..... | 5        |
| 1.3. SCOPE OF REVIEW.....                            | 5        |
| <b>2. REGULATORY REVIEW .....</b>                    | <b>5</b> |
| <b>3. COMPLIANCE REVIEW .....</b>                    | <b>5</b> |
| <b>4. SCIENTIFIC REVIEW .....</b>                    | <b>6</b> |
| 4.1. CHEMISTRY.....                                  | 6        |
| 4.2. TOXICOLOGY.....                                 | 6        |
| <b>5. ENVIRONMENTAL DECISION.....</b>                | <b>7</b> |
| <b>6. CONCLUSION AND RECOMMENDATION .....</b>        | <b>7</b> |

## 1. BACKGROUND

### 1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

| SE0014891: Chesterfield Menthol Box |                       |
|-------------------------------------|-----------------------|
| Product Name                        | Basic Menthol Box     |
| Package Type                        | Hard Pack             |
| Package Quantity                    | 20 Cigarettes         |
| Length                              | 83 mm                 |
| Diameter <sup>1</sup>               | 7.89 mm               |
| Ventilation                         | 0%                    |
| Characterizing Flavor               | Menthol               |
| SE0014892: Chesterfield Box         |                       |
| Product Name                        | Basic Full Flavor Box |
| Package Type                        | Hard Pack             |
| Package Quantity                    | 20 Cigarettes         |
| Length                              | 83 mm                 |
| Diameter <sup>1</sup>               | 7.89 mm               |
| Ventilation                         | 0%                    |
| Characterizing Flavor               | None                  |
| SE0014906: Chesterfield Menthol Box |                       |
| Product Name                        | Basic Menthol Box     |
| Package Type                        | Hard Pack             |
| Package Quantity                    | 20 Cigarettes         |
| Length                              | 83 mm                 |
| Diameter <sup>1</sup>               | 7.89 mm               |
| Ventilation                         | 0%                    |
| Characterizing Flavor               | Menthol               |

| <b>SE0014907: Chesterfield Box</b> |                       |
|------------------------------------|-----------------------|
| <b>Product Name</b>                | Basic Full Flavor Box |
| <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                  |

The predicate tobacco products are combusted, filtered cigarettes manufactured by the applicant.

## **1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW**

On October 17, 2018 and October 19, 2018, FDA received five SE Reports from Altria Client Services LLC, on behalf of Philip Morris USA Inc. FDA issued an Acknowledgment letter to the applicant on October 26, 2018.

## **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 Maria Suarez on October 25, 2018, and by Ebony Jackson on October 26, 2018.

The final reviews conclude that the SE Reports are administratively complete.

## **3. COMPLIANCE REVIEW**

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate tobacco products are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews dated November 5, 2018, November 13, 2018, and November 14, 2018, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered and, therefore, 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), as required by section 905(j)(1)(A)(i) of the FD&C Act. The OCE review dated January 10, 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

A chemistry review was completed by Jianping Gong on November 30, 2018.

The chemistry review concludes that the new tobacco products have different characteristics related to product chemistry compared to the 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:

- Ingredient changes in the base tipping paper, tipping inks, and tipping ink extenders

The new and corresponding predicate tobacco products only differ in tipping papers which is the non-combusted portion of the tobacco products. These changes are not expected to impact the smoke chemistry. 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 Theresa Thekkudan on December 10, 2018.

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

- (b) (4) increase in (b) (4) (SE0014906 and SE0014907)
- (b) (4) increase in (b) (4)
- (b) (4) increase in (b) (4)
- (b) (4) increase in (b) (4)
- Addition of (b) (4)
- Addition of (b) (4)
- Addition of (b) (4)
- Addition of (b) (4)
- Addition of (b) (4)
- Addition of (b) (4)

The above ingredient changes occur in the surface tipping components of the cigarette that are not expected to be heated or burned, therefore they are unlikely to be pyrolyzed or contribute to the inhaled mainstream smoke of the cigarette. However, they may lead to oral

or dermal exposure through contact with the tipping paper, tipping ink, and tipping ink extender. The toxicology review evaluated the amount of each ingredient increase or addition and determined that the increased and added ingredients would result in exposure below the established exposure limits. The toxicology review concluded that the increased and added ingredients do not cause the new products 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 toxicology perspective.

## 5. ENVIRONMENTAL DECISION

An environmental review was completed by William Brenner on November 19, 2018.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on January 14, 2019. The FONSI was supported by an environmental assessment prepared by FDA on January 14, 2019.

## 6. CONCLUSION AND RECOMMENDATION

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

- (b) (4) increase in (b) (4) (SE0014906 and SE0014907)
- (b) (4) increase in (b) (4)
- (b) (4) increase in (b) (4)
- (b) (4) increase in (b) (4)
- Addition of (b) (4)
- Addition of (b) (4)
- Addition of (b) (4)
- Addition of (b) (4)
- Addition of (b) (4)
- Addition of (b) (4)

All of the above ingredient changes are in the base tipping paper, tipping inks, and tipping ink extenders. These changes are not expected to be heated or burned, therefore they are unlikely to be pyrolyzed or contribute to the inhaled mainstream smoke of the cigarette. However, they may lead to oral or dermal exposure through contact with the tipping paper, tipping ink, and tipping ink extender. The toxicology review concluded that the increased and added ingredients do not cause the new products to raise different questions of public health. The toxicology review evaluated the amount of each ingredient increase or addition and determined that the increased and added ingredients result in exposure below the established exposure limits. For example, for iron hydroxide oxide added into the new products, the potential maximum exposure level is below the Joint FAO/WHO Expert Committee on Food Additive's (JECFA) acceptable daily intake (ADI) level.

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 meet statutory requirements because it was determined that they are grandfathered tobacco products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

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 SE0014891, SE0014892, SE0014906, and SE0014907, as identified on the cover page of this review.