Technical Project Lead (TPL) Review: SE0014815, SE0014816, SE0014817, and SE0014818

SE0014815: Chesterfield Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	None
SE0014816: Chesterfield Menthol Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
SE0014817: Chesterfield Menthol 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
SE0014818: Chesterfield 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Philip Morris USA Inc.
Report Type	Regular
Product Category	Cigarettes
Product Sub-Category	Combusted Filtered
Recommendation	
Issue a Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Melissa Mcculloch -S
Date: 2018.09.26 09:05:20 -04'00'

Melissa McCulloch, Ph.D.
Senior Regulatory Scientist
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: 2018.09.27 08:41:25 -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:

SE0014815: Chesterfield Box	
Product Name	Basic Full Flavor Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	None
SE0014816: Chesterfield Menthol Box	
Product Name	Basic Menthol Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
SE0014817: Chesterfield Menthol 100's Box	
Product Name	Basic Menthol 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
SE0014818: Chesterfield 100's Box	
Product Name	Basic Full Flavor 100's Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On July 12, 2018, FDA received four SE Reports, from Altria Client Services LLC (ALCS), on behalf of Philip Morris USA Inc. (PMUSA). FDA issued Acknowledgement letters to the applicant on July 19, 2018.

Product Name	SE Report	Amendments
Chesterfield Box	SE0014815	None
Chesterfield Menthol Box	SE0014816	
Chesterfield Menthol 100's Box	SE0014817	
Chesterfield 100's Box	SE0014818	

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 Grace Kaiyuan on July 19, 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 review dated August 17, 2018, concludes 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 September 18, 2018 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 Jikun Liu on August 27, 2018.

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 in the new tobacco products compared to the corresponding predicate tobacco products:

- Tipping paper:

  - Addition of (b)(4)
  - Removal of (b)(4)
  - (b)(4) decreased 90% (b) (4) µg/cigarette)
- Tipping ink:
  - Addition of
  - Removal of
  - increased between 257% and 320% µg/cigarette)
  - increased between 273% and 323% /cigarette)
  - decreased between 17% and 46%)
- Tipping ink extender:
  - Addition of
  - Removal of
  - decreased between 10% and 29% /cigarette)

As noted above, there are several ingredient differences between the new and corresponding predicate tobacco products. All ingredients that were added or increased in the new tobacco products compared to the corresponding predicate tobacco products are present in amounts below 1 mg/cigarette and, therefore, are unlikely to impact smoke chemistry. Additionally, the removal of the ingredients listed above will not negatively impact smoke chemistry. Further, base tipping papers, tipping inks and tipping ink extenders are not combusted during normal cigarette use and, therefore, changes to their compositions are not expected to affect smoke chemistry, including harmful and potentially harmful constituents (HPHCs). 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 Cissy Li on August 30, 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 toxicology review identified the same differences between the new and corresponding predicate tobacco products as discussed in the chemistry section (Section 4.1) above.

The toxicology review determined that all ingredient differences occur in the surface tipping components of the cigarette that are not expected to be heated or burned, therefore they are unlikely to pyrolyze or contribute to the inhaled mainstream smoke of the cigarette. However, they may lead to oral, buccal, or dermal exposure through contact with the tipping paper, tipping ink, or tipping ink extender. Where applicable, the toxicology review evaluated the

amount of each ingredient increase or addition to calculate daily exposure amounts and determined that the increased and added ingredients result in exposures below established exposure limits. Some ingredients do not have established exposure limits; in these instances, the toxicology review evaluated the amount of the ingredient increase or addition and determined that the ingredient increases or added amounts were small and would not result in significant exposures. 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

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on September 6, 2018. The FONSI was supported by an environmental assessment prepared by FDA on September 6, 2018.

6. CONCLUSION AND RECOMMENDATION

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

- Tipping paper:
  - Addition of
  - 90% decrease in
- Tipping ink:
  - Addition of
  - Removal of
  - 257% to 320% increase in
  - 273% to 323% increase in
  - 17% to 46% decrease in
- Tipping ink extender:
  - Addition of
  - Removal of
  - 10% to 29% decrease in

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The applicant reported ingredient information for the tipping papers, tipping inks and tipping ink extenders, which indicates modifications have been made to the compositions of the three tipping components of all the new tobacco products. The applicant provides a certification statement for all SE Reports that, except for the three tipping components mentioned above, the materials, ingredients, design features, heating source, or any other feature of the new tobacco product are identical to those of the corresponding predicate tobacco products. As noted above, there are several ingredient differences between the

new and corresponding predicate tobacco products. The removal of the ingredients listed above will not negatively impact smoke chemistry. Additionally, all ingredients that were added to or increased in the new tobacco product compared to the corresponding predicate tobacco product are present in amounts below 1 mg/cigarette and, therefore, are unlikely to impact smoke chemistry. Further, base tipping papers, tipping inks and tipping ink extenders are unlikely to pyrolyze or contribute to the inhaled mainstream smoke during normal cigarette use. Therefore, changes to the composition of base tipping papers, tipping inks and tipping ink extenders are not expected to affect smoke chemistry, including HPHCs. However, these ingredients may lead to oral, buccal, or dermal exposure through contact with the tipping paper, tipping ink, or tipping ink extender. Where applicable, the amount of each ingredient increase or addition was used to calculate a daily exposure amount and determined that the increased and added ingredients result in exposures well below established exposure limits. Some ingredients do not have established exposure limits; in these instances, the toxicology review evaluated the amount of the ingredient increase or addition and determined that the ingredient increases or added amounts were small and would not result in significant exposures. Therefore, the differences in characteristics between the new and corresponding predicate 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 SE0014815, SE0014816, SE0014817, and SE0014818 as identified on the cover page of this review.