Technical Project Lead (TPL) Review: SE0015058 and SE0015059

SE0015058: Chesterfield Blue Pack 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98.5 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None
SE0015059: Chesterfield Blue Pack Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	18%
Characterizing Flavor	None
Common 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.	

Technical Project Lead (TPL):

Digitally signed by Jeannie H. Jeong-im -S
Date: 2019.04.05 10:31:19 -04'00'

Jeannie Jeong-Im, 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: 2019.04.08 06:44:13 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0015058: Chesterfield Blue Pack 100's Box	
Product Name	Basic Lights 100s Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98.5 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None
SE0015059: Chesterfield Blue Pack Box	
Product Name	Basic Lights Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	18%
Characterizing Flavor	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On January 15, 2019, FDA received SE Reports (SE0015058 - SE0015059), from Altria Client Services (ALCS) on behalf of Philip Morris USA, Inc. FDA issued an Acknowledgement letter on January 22, 2019 for both STNs.

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 Ester Hatton on January 22, 2019.

The reviews concluded that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review 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 February 8, 2019 and February 21, 2019, 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) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated April 3, 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 Salome Bhagan on March 5, 2019.

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:

- Changes in composition of the base tipping paper, which include 211% higher (b)(4) [redacted] 64% lower (b)(4) [redacted], and 3% lower (b)(4) [redacted]
- Deletion of two ink extenders
- Addition of 50% lower quantity of a new extender; the extenders in the new tobacco product include small quantities of less than 0.2 mg/cig of (b)(4) [redacted] and less than 0.05 mg/cig each of (b)(4) [redacted] and (b)(4) [redacted]
- Deletion of brown, gold, and buff tipping inks
- Addition of blue tipping ink (b) (4) mg/cig; 0.02%/cig)
- Addition of lip release agents (b) (4) mg/cig; 0.03%/cig)
- 2% (b) (4) mg/cig) decrease in overall cigarette mass due to changes in the base tipping papers, tipping inks, tipping ink extenders, and addition of lip releases

The applicant only provided information on the ingredients in the base tipping papers, tipping inks, tipping ink extenders, and lip releases in the new and corresponding predicate tobacco products. The applicant did not clearly identify the component changes that resulted in an overall (b) (4) mg/cig lower mass difference in the cigarette between the new and corresponding predicate products. However, based on the applicant's certification statement (i.e., "…no other modification to the materials, ingredients, design features, heating source, or any other feature of the new product."), the net decrease in cigarette mass is attributed solely to the changes to the base tipping papers (i.e., 211% higher (b)(4) [redacted] 64% lower (b)(4) [redacted] 3% lower (b)(4) [redacted]), tipping inks (i.e., deletion of brown, gold, and

buff tipping inks, addition of blue tipping ink), ink extenders (i.e., deletion of two ink extenders, addition of 50% lower quantity of a new extender), and lip release agents (i.e., addition of lip releases agent). Therefore, the changes to the base tipping papers, tipping inks, extenders, and addition of lip releases in the new tobacco products compared to the corresponding predicate products do not cause the new products to raise different questions of public health.

4.2. TOXICOLOGY

A toxicology review was completed by Mary Irwin on March 4, 2019.

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

- Differences in the tipping paper ingredients

These ingredients are found in the portion of the products that are not expected to undergo combustion during normal use; therefore, it is unlikely that there would be any inhalation exposure by the user. In addition, because the base tipping paper and associated components (inks, ink extenders, and lip release) are not likely to be released from the paper matrix, exposure to these components by the oral or dermal routes is expected to be minimal. 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 science review was completed by William Brenner on February 12, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 4, 2019. The FONSI was supported by an environmental assessment prepared by FDA on April 4, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Base tipping paper:
  - 211% higher [redacted]
  - 64% lower [redacted]
  - 3% lower [redacted]
- Deletion of two ink extenders
- Addition of 50% lower quantity of a new extender
- Deletion of brown, gold, and buff tipping inks
- Addition of blue tipping ink (b) (4) mg/cig; 0.02% per cig)
- Addition of lip release agents (b) (4) mg/cig; 0.03% per cig)
- 2% (b) (4) mg/cig) decrease in overall cigarette mass due to changes in the base tipping papers, tipping inks, tipping ink extenders, and addition of lip releases

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. [redacted] is 211% higher, while [redacted] and [redacted] were 64% and 3%, respectively, lower in the new products. These are a change from (b) (4) mg/cig to (b) (4) mg/cig in the new product. Also, there is an addition of ink extenders; addition of 50% lower quantity of ink extenders; deletion of brown, gold, and buff tipping inks; addition of blue tipping ink; and addition of lip release agents that resulted in a 2% decrease in overall cigarette mass. The tipping papers are not combusted; thus, these changes are not expected to significantly alter the smoke chemistry. 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 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 SE0015058 and SE0015059, as identified on the cover page of this review.