

Technical Project Lead (TPL) Review:

SE0014858 and SE0014859

SE0014858: Marlboro Menthol Slate 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter ¹	7.64 mm
Ventilation	17%
Characterizing Flavor	Menthol
SE0014859: Marlboro Menthol Slate Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter ¹	7.89 mm
Ventilation	23%
Characterizing Flavor	Menthol
Common Attributes of SE Reports	
Applicant	Philip Morris USA Inc.
Report Type	Regular
Product Category	Cigarettes
Product Sub-Category	Combusted, Filtered
Recommendation	
Issue Substantially Equivalent (SE) orders.	

¹ The applicant submitted the circumference which allowed for a calculation of diameter.

Technical Project Lead (TPL):

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Date: 2019.02.13 11:43:23 -05'00'

Kenneth M. Taylor, 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: 2019.02.13 13:25:56 -05'00'

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:

SE0014858: Marlboro Menthol Slate 100's Box	
Product Name	Players 100's Menthol Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter ¹	7.64 mm
Ventilation	17%
Characterizing Flavor	Menthol
SE0014859: Marlboro Menthol Slate Box	
Product Name	Players Kings Menthol Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter ¹	7.89 mm
Ventilation	23%
Characterizing Flavor	Menthol

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On August 22, 2018, FDA received two SE Reports submitted by Altria Client Services LLC (ALCS) on behalf of Philip Morris USA Inc. (PM USA). FDA issued an Acknowledgement letter to the applicant on August 29, 2018. FDA issued an Advice/Information (A/I) Request letter on November 6, 2018. On November 19, 2018, FDA received the response to the A/I Request letter (SE0014973).

Product Name	SE Report	Amendments
Marlboro Menthol Slate 100's Box	SE0014858	SE0014973
Marlboro Menthol Slate Box	SE0014859	SE0014973

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 Arielle Patno on August 29, 2018.

The 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 September 18, 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 (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated January 31, 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 An Vu on September 28, 2018.

The final 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:

- 211% increase in (b)(4) .

The increase in (b)(4) quantity used in the new tipping papers (b)(4) (↑ 211%) compared to the predicate tipping papers could raise toxicological concerns. The differences in the amount of (b)(4) was deferred to the toxicology review to determine whether it causes the new tobacco products to raise different questions of public health. Nonetheless, these tipping materials are not combusted during smoking and are thus not expected to contribute to harmful and potentially harmful constituents (HPHC) smoke yields. Moreover, the different tipping paper compositions do not alter filter ventilation and are thus unlikely to affect smoke delivery.

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

Toxicology reviews were completed by Theresa Thekkudan on October 25, 2018 and January 08, 2019.

The final 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:

- Ingredients were increased or added to the tipping paper, tipping inks, and tipping ink extenders:
 - 33-36% increase in (b)(4) (SE0014858 and SE0014859)
 - 145-156% increase in (b)(4) (SE0014858 and SE0014859)
 - 185-202% increase in (b)(4) (SE0014858 and SE0014859)
 - 5% increase in (b)(4) / (b)(4) (SE0014858 and SE0014859)
 - 9% increase in (b)(4) (SE0014858)
 - 9% increase in (b)(4) (SE0014858)
 - 8-15% increase in (b)(4) (SE0014858 and SE0014859)
 - 8-9% increase in (b)(4) (SE0014858 and SE0014859)
 - 9% increase in (b)(4) (SE0014858)
 - 232-233% increase in (b)(4) (SE0014858 and SE0014859)
 - 197-198% increase (b)(4) (SE0014858 and SE0014859)
 - Addition of (b)(4) (SE0014858 and SE0014859).

The ingredient differences occur in components that are not combusted and as a result are unlikely to be pyrolyzed or contribute to the inhaled mainstream smoke of the new tobacco products. However, there may be oral, buccal, or dermal exposure through user contact with the tipping paper, tipping ink, and tipping ink extenders. Most of these ingredients are at levels that are significantly less than risk exposure levels to cause concern. The applicant reported higher amounts of (b)(4) in the tipping paper of both new products and in the tipping ink of the new product for SE0014859. The applicant provided statements from their supply vendors that the median particle diameter of (b)(4) is (b)(4) nm in the tipping paper and (b)(4) nm in the tipping inks. Given the reported particle sizes, the (b)(4) in the tipping paper and associated inks of the new products are larger than those thought to potentially cause toxicity because they are unlikely to be released from the tipping paper matrix.

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

Environmental reviews were completed by Shannon Hanna on October 11, 2018 and William Brenner on January 2, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on February 13, 2019. The FONSI was supported by an environmental assessment prepared by FDA on February 13, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Ingredients were increased or added to the tipping paper, tipping inks, and tipping ink extenders:
 - 33-36% increase in (b)(4) (SE0014858 and SE0014859)
 - 145-156% increase in (b)(4) (SE0014858 and SE0014859)
 - 185-202% increase in (b)(4) (SE0014858 and SE0014859)
 - 5% increase in (b)(4) / (b)(4) (SE0014858 and SE0014859)
 - 9% increase in (b)(4) (SE0014858)
 - 9% increase in (b)(4) (SE0014858)
 - 8-15% increase in (b)(4) (SE0014858 and SE0014859)
 - 8-9% increase in (b)(4) (SE0014858 and SE0014859)
 - 9% increase in (b)(4) (SE0014858)
 - 232-233% increase in (b)(4) (SE0014858 and SE0014859)
 - 197-198% increase of (b)(4) (SE0014858 and SE0014859)
 - Addition of (b)(4) (SE0014858 and SE0014859).

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The ingredient changes are in tipping material components (tipping inks, tipping ink extenders, and tipping papers) which are not combusted during smoking. As a result, the ingredient differences are not expected to contribute to HPHC smoke yields. The toxicology review also concludes that the particle size of (b)(4) will cause it to remain bound to the tipping paper matrix and that any oral or dermal exposure will not be sufficient to cause a concern from normal use of the new products. 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 SE0014858 and SE0014859, as identified on the cover page of this review.