# Technical Project Lead (TPL) Review: SE0014203

| SE0014203: Marlboro Menthol Gold Pack Box | |
|---|---|
| **Package Type** | Hard Pack |
| **Package Quantity** | 20 Cigarettes |
| **Length** | 83 mm |
| **Diameter** | 7.89 mm |
| **Filter Ventilation** | 34% |
| **Characterizing Flavor** | Menthol |
| **Common Attributes of SE Reports** | |
| **Applicant** | Philip Morris USA, Inc. |
| **Report Type** | Regular |
| **Product Category** | Cigarette |
| **Product Sub-Category** | Filtered Combusted |
| **Recommendation** | |
| **Issue a Substantially Equivalent (SE) order.** | |

**Technical Project Lead (TPL):**

Matthew J. Walters -S
2018.03.01 17:46:03 -05'00'

Matthew J. Walters, Ph.D., MPH
CDR, U.S. Public Health Service
Deputy Director
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: 2018.03.01 18:41:05 -05'00'

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

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# 1. BACKGROUND

## 1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

| SE0014203: Marlboro Menthol Gold Pack Box | |
|---|---|
| **Product Name** | Marlboro Lights Menthol Box |
| **Package Type** | Hard Pack |
| **Package Quantity** | 20 Cigarettes |
| **Length** | 83 mm |
| **Diameter** | 7.89 mm |
| **Filter Ventilation** | 34% |
| **Characterizing Flavor** | Menthol |

The predicate tobacco product are combusted filtered cigarettes manufactured by the applicant, Philip Morris USA, Inc.

## 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On July 18, 2017, on behalf of Philip Morris USA Inc., Altria Client Services LLC submitted the Substantial Equivalence (SE) Report for the tobacco product listed above. On July 24, 2017, FDA acknowledged the SE Report. On August 17, 2017, FDA received an unsolicited amendment (SE0014243) with a correction to the environmental assessment. On October 16, 2017, FDA issued an Advice/Information (A/I) Request letter. On December 1, 2017, FDA received a response (SE0014424) to the A/I Request letter. On February 9, 2018, FDA received an amendment from the applicant (SE0014508) containing an update to the (b)(4) and (b)(4) amounts in the Ingredient Comparison table in the original SE Report. As this amendment was received after all scientific reviews were completed, FDA did not include this amendment in the scientific reviews. However, I have examined the amendment and determined that this amendment does not alter the conclusions of the scientific reviews on this SE Report. The amendment simply clarified the quantities of (b)(4) and (b)(4) explaining that the new and predicate tobacco products contain identical quantities.

| Product Name | SE Report | Amendment |
|---|---|---|
| Marlboro Menthol Gold Pack Box | SE0014203 | SE0014243<br>SE0014424<br>SE0014508 |

## 1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for this SE Report.

## 2. REGULATORY REVIEW

A regulatory review was completed by Iqra Javaid on July 24, 2017.

The final review conclude that the SE Report is 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 product is a grandfathered product (i.e., was commercially marketed as of February 15, 2007). The OCE review dated August 21, 2017, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and, therefore, is an eligible predicate tobacco product.

OCE also completed a review to determine whether the new tobacco product is in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see section 910(a)(2)(i)(II) of the FD&C Act). The OCE review dated January 30, 2018, concludes that the new tobacco product is in compliance with the FD&C Act.

## 4. SCIENTIFIC REVIEW

A scientific review was completed by the Office of Science (OS) for the following discipline:

### 4.1. CHEMISTRY

A chemistry review was completed by Delshanee Kotandeniya on October 16, 2017.

The final chemistry review concludes that the new tobacco product has different characteristics related to product composition compared to the predicate tobacco product but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following difference related to product composition:

- The predicate product contains (b)(4) ng/cigarette of (b)(4) as a flavor ingredient while the new product does not contain this flavor ingredient

## 5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on March 1, 2018. The FONSI was supported by an environmental assessment prepared by FDA on March 1, 2018.

## 6. CONCLUSION AND RECOMMENDATION

The following is the key difference in characteristics between the new and predicate tobacco products:

- The predicate product contains (b)(4) ng/cigarette of (b)(4) as a flavor ingredient while the new product does not contain this flavor ingredient

The applicant has demonstrated that this difference in characteristics does not cause the new tobacco product to raise different questions of public health. This SE Report included minimal information about the tobacco blend and ingredients other than tobacco for the new and predicate products. However, the applicant provided ingredients other than tobacco for the new and predicate products along with a certification statement signed by a responsible official authorized to act on behalf of the company (PMUSA) that stated that "the characteristics of the new and predicate product are identical in all aspects with the exception...of (b)(4) The only modification between the new and predicate product is the removal of the flavor ingredient (b)(4) in the new product, and this modification is not expected to impact smoke chemistry. Therefore, the difference in characteristics between the new and predicate products does not cause the new tobacco product to raise different questions of public health.

The predicate tobacco product meets statutory requirements because it is a grandfathered product (i.e., was commercially marketed in the United States as of February 15, 2007).

The new tobacco product is currently in compliance with the FD&C Act. In addition, the chemistry review concludes that the difference between the new and predicate tobacco products is such that the new tobacco product does not raise different questions of public health. I concur with this review and recommend that an SE order letter be issued.

FDA examined the environmental effects of finding the new tobacco product substantially equivalent and made a finding of no significant impact.

An SE order letter should be issued for the new tobacco product in SE0014203, as identified on the cover page of this review.