FDA U.S. FOOD & DRUG ADMINISTRATION

# Technical Project Lead (TPL) Review:

# SE0014849, SE0014850, SE0014851, and SE0014852

| | |
|---|---|
| **SE0014849: Marlboro Red Label 100's Box** | |
| **Package Type** | Hard Pack |
| **Package Quantity** | 20 Cigarettes |
| **Length** | 98.5 mm |
| **Diameter** | 7.89 mm |
| **Ventilation** | 20% |
| **Characterizing Flavor** | None |
| **SE0014850: Marlboro Special Select (Red Pack) Box** | |
| **Package Type** | Hard Pack |
| **Package Quantity** | 20 Cigarettes |
| **Length** | 84 mm |
| **Diameter** | 7.89 mm |
| **Ventilation** | 20% |
| **Characterizing Flavor** | None |
| **SE0014851: Marlboro Red Label Box** | |
| **Package Type** | Hard Pack |
| **Package Quantity** | 20 Cigarettes |
| **Length** | 83 mm |
| **Diameter** | 7.89 mm |
| **Ventilation** | 20% |
| **Characterizing Flavor** | None |
| **SE0014852: Marlboro Special Select (Red Pack) 100's Box** | |
| **Package Type** | Hard Pack |
| **Package Quantity** | 20 Cigarettes |
| **Length** | 99.5 mm |
| **Diameter** | 7.89 mm |
| **Ventilation** | 20% |
| **Characterizing Flavor** | None |
| **Common Attributes of SE Reports** | |
| **Applicant** | Philip Morris USA Inc. |
| **Report Type** | Regular |
| **Product Category** | Cigarettes |
| **Product Sub-Category** | Combusted, Filtered |
| **ecommendation** | |
| Issue Substantially Equivalent (SE) orders. | |

**Technical Project Lead (TPL):**

Digitally signed by Kenneth Taylor -S
Date: 2019.02.13 12:13:03 -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 14:08:44 -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:

| **SE0014849: Marlboro Red Label 100's Box** | |
|---|---|
| **Product Name** | Marlboro Medium 100's Box |
| **Package Type** | Hard Pack |
| **Package Quantity** | 20 Cigarettes |
| **Length** | 98.5 mm |
| **Diameter** | 7.89 mm |
| **Ventilation** | 20% |
| **Characterizing Flavor** | None |
| **SE00148S0: Marlboro Special Select (Red Pack) Box** | |
| **Product Name** | Marlboro Medium Soft Pack |
| **Package Type** | Soft Pack |
| **Package Quantity** | 20 Cigarettes |
| **Length** | 84 mm |
| **Diameter** | 7.89 mm |
| **Ventilation** | 20% |
| **Characterizing Flavor** | None |
| **SE0014851: Marlboro Red Label Box** | |
| **Product Name** | Marlboro Medium Box |
| **Package Type** | Hard Pack |
| **Package Quantity** | 20 Cigarettes |
| **Length** | 83 mm |
| **Diameter** | 7.89 mm |
| **Ventilation** | 20% |
| **Characterizing Flavor** | None |
| **SE00148S2: Marlboro Special Select (Red Pack) 100's Box** | |
| **Product Name** | Marlboro Medium 100's Soft Pack |
| **Package Type** | Soft Pack |
| **Package Quantity** | 20 Cigarettes |
| **Length** | 99.5 mm |
| **Diameter** | 7.89 mm |
| **Ventilation** | 20% |
| **Characterizing Flavor** | None |

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

### 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On August 8, 2018, FDA received four SE Reports from Altria Client Services LLC, on behalf of Philip Morris USA Inc. FDA issued an Acknowledgment letter for all STNs on August 15, 2018. FDA issued an Advice/Information Request (A/I) letter for all of the STNs on October 29, 2018. On November 19, 2018, FDA received the applicant's response to the A/I Request letter (SE0014975).

| Product Name | SE Report | Amendments |
|---|---|---|
| Marlboro Red Label 100's Box | SE0014849 | SE0014975 |
| Marlboro Special Select (Red Pack) Box | SE0014850 | SE0014975 |
| Marlboro Red Label Box | SE0014851 | SE0014975 |
| Marlboro Special Select (Red Pack) 100's Box | SE0014852 | SE0014975 |

### 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 Sarah Webster on August 15, 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 reviews dated September 11, 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 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 Youbang Liu on September 20, 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 difference:

- 211% increase in (b) (4) in the base tipping papers

The base tipping paper is a component that is not intended to be combusted during use of the tobacco products and the increase in (b) (4) will not contribute to smoke chemistry.

Therefore, the difference 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 Eric Beier on October 17, 2018, and on January 9, 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:

- Addition of the following ingredients to the tipping paper, tipping inks, and ink extender
  - (b) (4)
  - (b) (4)
  - (b) (4)
  - (b) (4)
  - (b) (4)
  - (b) (4)
- 211% increase in (b) (4) in the base tipping papers

These ingredient differences are in non-combusted components of the new tobacco products and are not expected to be inhaled. Additionally, these ingredients are expected to remain bound in the component matrices and exposure via oral or dermal routes is anticipated to be minimal and below levels that would cause concerns.

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 William Brenner on September 25, 2018, and on December 14, 2018.

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:

- Addition of the following ingredients to the tipping paper, tipping inks, and ink extenders
  - (b) (4)
  - (b) (4)
  - (b) (4)
  - (b) (4)
  - (b) (4)
  - (b) (4)
- 211% increase in (b) (4) in the base tipping papers

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. All ingredient changes in the new tobacco products are in either the tipping paper, tipping ink, or tipping ink extenders; all of which are intended to be non-combusted during use. As a result, smoke chemistry is anticipated to be unaffected by these ingredient changes. Additionally, dermal and oral exposure amounts are also anticipated to be at levels that will not cause concerns. 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 SE0014849, SE0014850, SE0014851, and SE0014852, as identified on the cover page of this review.