

## Technical Project Lead (TPL) Review:

SE0014889, SE0014905, and SE0014908

SE0014889: Marlboro Menthol Black Special Blend 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.89 mm
Ventilation	16%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 1
SE0014905: Marlboro Menthol Black Special Blend 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.89 mm
Ventilation	16%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 2
SE0014908: Marlboro Menthol Black Special Blend 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.89 mm
Ventilation	16%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 3
Common Attributes of SE Reports	
Applicant	Philip Morris USA
Report Type	Regular
Product Category	Cigarettes
Product Sub-Category	Combusted, Filtered
Recommendation	
Issue Substantially Equivalent (SE) orders.	

**Technical Project Lead (TPL):**

Digitally signed by Kenneth Taylor -S  
Date: 2019.01.15 11:06:05 -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)

Matthew R.  
Holman -S

Digitally signed by Matthew R.  
Holman -S  
Date: 2019.01.15 11:29:16 -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:

<b>SE0014889: Marlboro Menthol Black Special Blend 100's Box</b>	
<b>Product Name</b>	Marlboro Menthol 100's Box
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	98 mm
<b>Diameter</b>	7.89 mm
<b>Ventilation</b>	16%
<b>Characterizing Flavor</b>	Menthol
<b>SE0014905: Marlboro Menthol Black Special Blend 100's Box</b>	
<b>Product Name</b>	Marlboro Menthol 100's Box
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	98 mm
<b>Diameter</b>	7.89 mm
<b>Ventilation</b>	16%
<b>Characterizing Flavor</b>	Menthol
<b>SE0014908: Marlboro Menthol Black Special Blend 100's Box</b>	
<b>Product Name</b>	Marlboro Menthol 100's Box
<b>Package Type</b>	Hard Pack
<b>Package Quantity</b>	20 cigarettes
<b>Length</b>	98 mm
<b>Diameter</b>	7.89 mm
<b>Ventilation</b>	16%
<b>Characterizing Flavor</b>	Menthol

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

### 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received Substantial Equivalence Reports (SE Reports) on October 17, 2018 for SE0014889, on October 19, 2018 for SE0014905, and on October 22, 2018 for SE0014908. On October 24, 2018, a teleconference was held between FDA and the applicant, in which the applicant confirmed the naming syntax for the tipping papers. FDA issued Acknowledgment Letters for these three SE Reports on October 25, 2018. On November 5, 2018, FDA received amendments (SE0014925, SE0014924, and SE0014923) for the three SE Reports respectively, correcting the predicate product name.

Product Name	SE Report	Amendments
Marlboro Menthol Black Special Blend 100's Box	SE0014889	SE0014925
Marlboro Menthol Black Special Blend 100's Box	SE0014905	SE0014924
Marlboro Menthol Black Special Blend 100's Box	SE0014908	SE0014923

### 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 Ebony Jackson on October 25, 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 as of February 15, 2007). The OCE reviews dated November 13, 2018 (for SE0014889) and November 14, 2018 (for SE0014905 and SE0014908), 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 10, 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

The chemistry review was completed by Selvin Edwards on December 6, 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 differences:

- Addition of (b) (4) [REDACTED] to the base tipping paper. Addition of (b) (4) [REDACTED] to the tipping inks. Addition of (b) (4) [REDACTED] to the tipping ink extenders. (SE0014889)
- Addition of (b) (4) [REDACTED] to the base tipping paper. Addition of (b) (4) [REDACTED] to the tipping inks and tipping inks extenders. (SE0014905)
- Addition of (b) (4) [REDACTED] to the tipping inks and tipping ink extenders. (SE0014908)

The differences in the ingredients reported for the new tobacco products compared to the corresponding predicate tobacco products are for absolute quantities that are less than (b) (4) [REDACTED] of the total product weights. In addition, the ingredient differences are largely restricted to the base tipping paper, tipping inks and tipping ink extenders, which are not combusted when the products are used as intended. As a result, the ingredient differences are not anticipated to affect the smoke chemistry of the new tobacco products.

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

The toxicology review was completed by Prabha Kc on December 6, 2018.

The 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:

- Overall addition of (b) (4) [REDACTED] the tipping ink and base tipping paper (SE0014889 and SE0014908) or tipping ink (SE0014908)
- (b) (4) [REDACTED] increase of (b) (4) [REDACTED] the base tipping paper (SE0014908)
- Addition of (b) (4) [REDACTED] in the base tipping paper (SE0014908)

- Addition of (b) (4) in the base tipping paper (SE0014908)
- (b) (4) Increase of (b) (4) in the tipping ink and tipping ink extenders (SE0014889, SE0014905, and SE0014908)
- Addition of (b) (4) in the tipping ink (SE0014889, SE0014905, and SE0014908)
- Addition of (b) (4) the base tipping paper (SE0014889)
- (b) (4) overall increase of (b) (4) in the base tipping paper and tipping ink (SE0014905)
- (b) (4) overall increase of (b) (4) in the tipping inks and tipping ink extenders (SE0014889, SE0014905, and SE0014908)
- Addition of (b) (4) in the base tipping paper (SE0014889)
- (b) (4) overall increase of (b) (4) in the tipping ink and tipping ink extender (SE0014889, SE0014905, and SE0014908)
- Overall addition of (b) (4) in the tipping ink and tipping ink extender (SE0014889, SE0014905, and SE0014908)
- Overall addition of (b) (4) in the tipping ink and tipping ink extender (SE0014889, SE0014905, and SE0014908)
- Addition of (b) (4) in the base tipping paper (SE0014905)
- Addition of (b) (4) in the base tipping paper (SE0014905)
- Addition of (b) (4) in the base tipping paper (SE0014905)
- (b) (4) overall increase of (b) (4) in the tipping ink and tipping ink extender (SE0014889, SE0014905, and SE0014908)
- Overall addition of (b) (4) in the tipping ink and tipping ink extender (SE0014889, SE0014905, and SE0014908)

The toxicology review concludes that the increased or added ingredients are in structural components of the cigarette that are not expected to be burned or pyrolyzed, and therefore will not contribute to the mainstream smoke of the cigarette. However, these ingredients may be contacted via oral or dermal exposure during smoking. Assuming consumption of 20 cigarettes per day and 100% absorption for a 60-kg or 70-kg person, the daily oral exposure to these ingredients from use of the new products is several folds lower than the no-observed-adverse-effect-level (NOAEL) and at minimum risk levels based on chronic rodent studies. As a result, minimal to no adverse effects are anticipated and there are no safety concerns from oral exposure.

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 January 11, 2019. The FONSI was supported by an environmental assessment prepared by FDA on January 11, 2019.

## 6. CONCLUSION AND RECOMMENDATION

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

- Addition of (b) (4) in the tipping ink and base tipping paper (SE0014889 and SE0014908) or tipping ink (SE0014908)
- (b) (4) increase of (b) (4) in the base tipping paper (SE0014908)
- Addition of (b) (4) in the base tipping paper (SE0014908)
- Addition of (b) (4) in the base tipping paper (SE0014908)
- (b) (4) Increase of (b) (4) in the tipping ink and tipping ink extenders (SE0014889, SE0014905, and SE0014908)
- Addition of (b) (4) in the tipping ink (SE0014889, SE0014905, and SE0014908)
- Addition of (b) (4) in the base tipping paper (SE0014889)
- (b) (4) overall increase of (b) (4) in the base tipping paper and tipping ink (SE0014905)
- (b) (4) overall increase of (b) (4) in the tipping inks and tipping ink extenders (SE0014889, SE0014905, and SE0014908)
- Addition of (b) (4) in the base tipping paper (SE0014889)
- (b) (4) overall increase of (b) (4) in the tipping ink and tipping ink extender (SE0014889, SE0014905, and SE0014908)
- Overall addition of (b) (4) in the tipping ink and tipping ink extender (SE0014889, SE0014905, and SE0014908)
- Overall addition of (b) (4) in the tipping ink and tipping ink extender (SE0014889, SE0014905, and SE0014908)
- Addition of (b) (4) in the base tipping paper (SE0014905)
- Addition of (b) (4) in the base tipping paper (SE0014905)
- Addition of (b) (4) in the base tipping paper (SE0014905)
- (b) (4) overall increase of (b) (4) in the tipping ink and tipping ink extender (SE0014889, SE0014905, and SE0014908)
- Overall addition of (b) (4) in the tipping ink and tipping ink extender (SE0014889, SE0014905, and SE0014908)

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 differences involve amounts that comprise typically about (b) (4) of the total tobacco products and are largely limited to the non-combusted components of the base tipping paper, tipping inks, and tipping ink extenders. As a result, the ingredient changes are not anticipated to affect the smoke chemistry of the new tobacco products. In consideration of oral exposure, the ingredients are at amounts that are several folds less than NOAELs. 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 SE0014889, SE0014905, and SE0014908 as identified on the cover page of this review.