

Technical Project Lead (TPL) Review:

**SE0014926, SE0014927, SE0014928, SE0014930, SE0014931,
SE0014932, SE0014933, SE0014934, and SE0014935**

SE0014926: Marlboro Menthol Special 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98.5 mm
Diameter ¹	7.89 mm
Ventilation	15%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 2
SE0014927: Marlboro Menthol Special Select Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter ¹	7.89 mm
Ventilation	18%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 1
SE0014928: Marlboro Menthol Special Select Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter ¹	7.89 mm
Ventilation	18%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 2
SE0014930: Marlboro Menthol Special Select 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98.5 mm
Diameter ¹	7.89 mm
Ventilation	15%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 1

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

SE0014931: L&M Menthol Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter ¹	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 1
SE0014932: Marlboro Menthol Green Pack 72's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	72 mm
Diameter ¹	7.89 mm
Ventilation	12%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 1
SE0014933: Marlboro Menthol Green Pack 72's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	72 mm
Diameter ¹	7.89 mm
Ventilation	12%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 2
SE0014934: L&M Menthol Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter ¹	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 2
SE0014935: L&M Menthol Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter ¹	7.89 mm
Ventilation	0%
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: 2019.02.04 16:01:00 -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: 2019.02.04 18:03:31 -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:

SE0014926: Marlboro Menthol Special Select 100's Box	
Product Name	Marlboro Milds 100's Menthol Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98.5 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	Menthol
SE0014927: Marlboro Menthol Special Select Box	
Product Name	Marlboro Milds Menthol Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	18%
Characterizing Flavor	Menthol
SE0014928: Marlboro Menthol Special Select Box	
Product Name	Marlboro Milds Menthol Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	18%
Characterizing Flavor	Menthol
SE0014930: Marlboro Menthol Special Select 100's Box	
Product Name	Marlboro Milds 100's Menthol Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98.5 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	Menthol

SE0014931: L&M Menthol Box	
Product Name	Basic Menthol Soft Pack
Package Type	SoftPack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
SE0014932: Marlboro Menthol Green Pack 72's Box	
Product Name	Marlboro Seventy-Twos Menthol (Green) Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	72 mm
Diameter	7.89 mm
Ventilation	12%
Characterizing Flavor	Menthol
SE0014933: Marlboro Menthol Green Pack 72's Box	
Product Name	Marlboro Seventy-Twos Menthol (Green) Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	72 mm
Diameter	7.89 mm
Ventilation	12%
Characterizing Flavor	Menthol
SE0014934: L&M Menthol Box	
Product Name	Basic Menthol Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol

SE0014935: L&M Menthol Box	
Product Name	Basic Menthol Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On November 6, 2018, FDA received 9 Substantial Equivalence (SE) Reports from Philip Morris USA Inc. (PMUSA). FDA issued an Acknowledgement letter to the applicant on November 15, 2018.

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 Antonio Thornton on November 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 December 4, 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 February 1, 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 December 19, 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:

- Increases (185%-212%) in (b) (4) in the tipping paper (SE0014926, SE0014927, SE0014928, SE0014930, SE0014932, and SE0014933)
- Addition of (b) (4) to the tipping paper (SE0014926 and SE0014928)
- Addition of (b) (4) to the tipping paper (SE0014931 and SE0014935)

The new tobacco products differ from the corresponding predicate tobacco products only in the composition and weight of tipping inks, tipping ink extenders, and tipping papers. Most ingredient changes associated with these tipping material modifications involve less than 0.1% of the total cigarette weight. However, there are some ingredient differences that involve larger amounts in the new tobacco products. (b) (4) increases 185% to 212% in the tipping paper of the new tobacco products of SE0014926, SE0014927, SE0014928, SE0014930, SE0014932, and SE0014933. (b) (4) are added to the tipping paper in the new tobacco products of SE0014926 and SE0014928; and (b) (4) is added to the tipping paper of the new tobacco products for SE0014931 and SE0014935. Because these tipping materials are not combusted during smoking, the ingredient differences are not expected to contribute to harmful and potentially harmful constituent (HPHC) smoke yields. Additionally, a toxicology consult concluded that the tipping paper constituents are anticipated 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.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on February 1, 2019. The FONSI was supported by an environmental assessment prepared by FDA on December 12, 2018.

6. CONCLUSION AND RECOMMENDATION

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

- Increases (185%-212%) in (b) (4) in the tipping paper (SE0014926, SE0014927, SE0014928, SE0014930, SE0014932, and SE0014933)
- Addition of (b) (4) to the tipping paper (SE0014926 and SE0014928)
- Addition of (b) (4) to the tipping paper (SE0014931 and SE0014935)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. Most of the ingredient changes associated with these tipping material modifications involve less than 0.1% of the total cigarette weight. Additionally, 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 consultation also concluded that the tipping paper constituents are anticipated 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 SE0014926, SE0014927, SE0014928, SE0014930, SE0014931, SE0014932, SE0014933, SE0014934, and SE0014935, as identified on the cover page of this review.