

Technical Project Lead (TPL) Review:

SE0014442, SE0014443, SE0014444, and SE0014445

SE0014442: Marlboro Menthol Gold Pack 100's Soft Pack	
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	99.5 mm
Diameter	7.89 mm
Ventilation	33%
Characterizing Flavor	Menthol
SE0014443: Marlboro Menthol Gold Pack Soft Pack	
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	34%
Characterizing Flavor	Menthol
SE0014444: Marlboro Menthol Gold Pack 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter	7.89 mm
Ventilation	33%
Characterizing Flavor	Menthol
SE0014445: Parliament Menthol (White Pack) Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	79 mm
Diameter	7.89 mm
Ventilation	23%
Characterizing Flavor	Menthol
Common Attributes of SE Reports	
Applicant	Philip Morris USA Inc.
Report Type	Regular
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Matthew J. Walters -S
2018.07.24 11:49:42 -04'00'

Matthew J. Walters, Ph.D., MPH
CDR, US 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: 2018.07.24 12:16:55 -04'00'

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:

SE0014442: Marlboro Menthol Gold Pack 100's Soft Pack	
Product Name	Marlboro Lights 100's Menthol Soft Pack
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	99.5 mm
Diameter	7.89 mm
Ventilation	33%
Characterizing Flavor	Menthol
SE0014443: Marlboro Menthol Gold Pack Soft Pack	
Product Name	Marlboro Lights Menthol Soft Pack
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	34%
Characterizing Flavor	Menthol
SE0014444: Marlboro Menthol Gold Pack 100's Box	
Product Name	Marlboro Lights 100's Menthol Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter	7.89 mm
Ventilation	33%
Characterizing Flavor	Menthol
SE0014445: Parliament Menthol (White Pack) Box	
Product Name	Parliament Menthol Lights Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	79 mm
Diameter	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 December 21, 2017, FDA received four SE Reports (SE0014442-SE0014445) from Altria Client Services LLC (ALCS) on behalf of Philip Morris USA Inc. (PM USA). FDA issued Acknowledgment letters on December 29, 2017. On February 9, 2018, FDA received unsolicited amendments (SE0014507, SE0014509-SE0014511), updating the ^{(b) (4)} amounts in the Ingredient Comparison Table in the original SE Reports. FDA issued an Advice and Information (A/I) letter on March 20, 2018. On May 1, 2018, FDA received an amendment (SE0014676) in response to the A/I letter.

Product Name	SE Report	Amendments
Marlboro Menthol Gold Pack 100's Soft Pack	SE0014442	SE0014509 SE0014676
Marlboro Menthol Gold Pack Soft Pack	SE0014443	SE0014507 SE0014676
Marlboro Menthol Gold Pack 100's Box	SE0014444	SE0014511 SE0014676
Parliament Menthol (White Pack) Box	SE0014445	SE0014510 SE0014676

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 Maria Suarez on December 29, 2017.

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 in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews dated January 17, 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 July 10, 2018, concludes that the new tobacco products are 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

Chemistry reviews were completed by Robert Gahl on February 28, 2018, and by Jikun Liu on June 8, 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:

- Removal of (b) (4) (flavor ingredient) from tobacco filler
- For SE0014443, the following differences in waxes used in filter seam adhesive:
 - 13% increase in (b) (4) (from (b) (4) mg/cig)
 - 125% increase in (b) (4) mg/cig)
 - 13% decrease in (b) (4) mg/cig)
 - Removal of (b) (4)

The only modification between the new and predicate products is the removal of the flavor ingredient (b) (4) in the new product for SE0014442, SE0014444, and SE0014445. The absence of (b) (4) in the new tobacco products is not expected to negatively impact smoke chemistry. However, for SE0014443, in addition to the removal of (b) (4) the applicant changed the type of wax used between the new and predicate tobacco products. The quantity change of the waxes in the filter seam adhesives for the new and predicate products is less than (b) (4) mg/cig, and part of a cigarette component that is not intended to be combusted during smoking. Therefore, the difference in characteristics between the new and corresponding predicate tobacco products does not cause the new tobacco products to raise different questions of public health related to product chemistry.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on July 18, 2018. The FONSI was supported by an environmental assessment prepared by FDA on July 18, 2018.

6. CONCLUSION AND RECOMMENDATION

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

- Removal of (b) (4) (flavor ingredient) from tobacco filler
- For SE0014443, the following differences in waxes used in filter seam adhesive:
 - 13% increase in (b) (4) mg/cig)
 - 125% increase in (b) (4) mg/cig)
 - 13% decrease in (b) (4) mg/cig)
 - Removal of (b) (4)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. These SE Reports 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 corresponding predicate products along with a certification statement signed by a responsible official authorized to act on behalf of the company (PMUSA) stating 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 products is the removal of the flavor ingredient (b) (4) in the new product for SE0014442, SE0014444, and SE0014445. The absence of (b) (4) in the new tobacco products is not expected to negatively impact smoke chemistry. However, for SE0014443, in addition to the removal of (b) (4) the applicant changed the wax used between the new and corresponding predicate tobacco products. The quantity change of the waxes in the filter seam adhesives for the new and predicate products is less than (b) (4) mg/cig, and part of a cigarette component that is not intended to be combusted during smoking. Therefore, the difference in characteristics between the new and corresponding predicate products does not cause the new tobacco products to raise different questions of public health.

The predicate tobacco products meet statutory requirements because 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 product is currently in compliance with the FD&C Act. In addition, the chemistry review concludes 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 this review and recommend that SE orders letter be issued.

FDA examined the environmental effects of finding the 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 SE0014442 – SE0014445, as identified on the cover page of this review.