FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review:

SE0014626 and SE0014627

SE0014626: Parliament Menthol (White Pack) 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	Menthol
SE0014627: Parliament Menthol (Silver Pack) Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	79 mm
Diameter	7.89 mm
Ventilation	47%
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):

Digitally signed by Kenneth Taylor -S
Date: 2018.06.27 14:37:44 -04'00'

Kenneth M. Taylor, Ph.D.
Chemistry Branch Chief
Division of Product Science

Signatory Decision:

X 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 Glen D. Jones -S
Date: 2018.06.28 19:20:14 -04'00'

For 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:

SE0014626: Parliament Menthol (White Pack) 100's Box	
Product Name	Parliament Menthol Lights 100's Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	Menthol
SE0014627: Parliament Menthol (Silver Pack) Box	
Product Name	Parliament Menthol Ultra Lights Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	79 mm
Diameter	7.89 mm
Ventilation	47%
Characterizing Flavor	Menthol

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On April 16, 2018, FDA received two SE Reports for the tobacco products listed above which were submitted by Altria Client Services Inc. (ALCS) on behalf of Philip Morris USA Inc. (PM USA). FDA acknowledged these SE Reports on April 23, 2018.

Product Name	SE Report	Amendments
Parliament Menthol (White Pack) 100's Box	SE0014626	None
Parliament Menthol (Silver Pack) Box	SE0014627	

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 Pin Zhang on April 23, 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 May 14, 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 June 14, 2018, 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 An Vu on May 23, 2018.

The 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 difference:

- Removal of (b) (4) (flavor ingredient) from tobacco filler

The new tobacco products have identical characteristics as the corresponding predicate tobacco products except that (b) (4) is not present in the tobacco filler. The removal of this ingredient should not affect smoke chemistry and HPHC yields of the new tobacco products in a negative way. 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. ENGINEERING

The engineering review was completed by Raymond Williamson on May 24, 2018.

The engineering review did not identify any differences in characteristics between the new and corresponding predicate tobacco products that could cause the new tobacco products to raise different questions of public health from an engineering perspective. Therefore, from an engineering perspective, the new and corresponding predicate tobacco products have identical characteristics and therefore do not cause the new tobacco products to raise different questions of public health related to product design.

4.3. TOXICOLOGY

The toxicology review was completed by Shaji Theodore on May 25, 2018.

The toxicology review concludes that the new tobacco products have different characteristics related to product 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 difference:

- Removal of (b) (4) (flavor ingredient) from the tobacco filler

This change is very small and is not likely to significantly alter the composition of the tobacco rod and thus unlikely to worsen the toxicological characteristics of the new tobacco products in comparison to the corresponding predicate tobacco products. Therefore, the removal of (b) (4) does not cause the new tobacco products to raise different questions of public health.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Mehran on June 22, 2018.

The environmental review found that information regarding the current and future status of the predicate tobacco products and the market volume information for the predicate tobacco products was not provided. Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI).

6. CONCLUSION AND RECOMMENDATION

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

- Removal of (b) (4) (flavor ingredient) from tobacco filler

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The removal of this single ingredient ((b) (4) which is present in minute amounts, is unlikely to have a significant impact on the new products or the smoke emitted from them. Therefore, this different characteristic 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 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 found additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing an SE order.

An Advice/Information Request letter should be issued requesting the following information:

1. Both of your SE Reports do not provide the current and future status of the predicate tobacco products. The status of the predicate tobacco products is used to fully assess the environmental impacts of the proposed actions of issuing marketing orders for the new tobacco products.
    a) Clarify if you are currently marketing the predicate tobacco products.
    b) Clarify if you intend to simultaneously market the predicate tobacco products after receiving marketing orders for the new tobacco products.

2. Both of your SE Reports lack market volume information for the predicate tobacco products. If you currently market the predicate tobacco products, provide the current market volumes. If you intend to simultaneously market the new and corresponding predicate tobacco products, provide the first-and fifth-year market volume projections for the predicate tobacco products. This information allows for an accurate assessment of the solid waste generated from disposal of the tobacco products. Provide the current market volumes and the first-and fifth-year market projections for the predicate tobacco products, if applicable, in Table 1.

Table 1: Market Volumes for the Predicate Tobacco Products

Market Share Information			
GF #	Current Market Volume (# of cigarettes)	First-Year Projected Market Volume (# of cigarettes)	Fifth-Year Projected Market Volume (# of cigarettes)
GF1200164			
GF1200166			

If the applicant adequately responds to the request and an EIS or FONSI is completed, SE order letters should be issued for the new tobacco products in SE0014626 and SE0014627, as identified on the cover page of this review.