FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0014725-SE0014726

SE0014725: Marlboro Menthol Soft Pack	
Package Type	Soft Pack
Package Quantity	20
Length	84 mm
Diameter	7.89 mm
Ventilation	21%
Characterizing Flavor	Menthol
SE0014726: Marlboro Menthol 100's Box	
Package Type	Hard Pack
Package Quantity	20
Length	98 mm
Diameter	7.89 mm
Ventilation	16%
Characterizing Flavor	Menthol
Common Attributes of SE Reports	
Applicant	Philips Morris USA Inc.
Report Type	Regular
Product Category	Cigarette
Product Sub-Category	Filtered Combusted
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Shixia Feng -S
Date: 2018.08.02 15:03:30 -04'00'

Shixia Feng, 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: 2018.08.06 12:18:51 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

TABLE OF CONTENTS

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0014725: Marlboro Menthol Soft Pack	
Product Name	Marlboro Menthol Soft Pack
Package Type	Soft Pack
Package Quantity	20
Length	84 mm
Diameter	7.89 mm
Ventilation	21%
Characterizing Flavor	Menthol
SE0014726: Marlboro Menthol 100's Box	
Product Name	Marlboro Menthol 100's Box
Package Type	Hard Pack
Package Quantity	20
Length	98 mm
Diameter	7.89 mm
Ventilation	16%
Characterizing Flavor	Menthol

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On May 16, 2018, FDA received two SE Reports from Altria Client Services LLC (ALCS) on behalf of Philip Morris USA Inc. (PM USA). FDA issued Acknowledgement letters to the applicant on May 23, 2018.

Product Name	SE Report	Amendments
Marlboro Menthol Soft Pack	SE0014725	N/A
Marlboro Menthol 100's Box	SE0014726	N/A

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 Samuel Motto on May 23, 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 in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews dated June 20, 2018, and July 18, 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 31, 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

Chemistry review was completed by Lida Oum on June 29, 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 difference:

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

The only modification between the new and predicate tobacco products is the removal of (b) (4) in the new tobacco products. The applicant provided certification statements stating that "there is no other modifications to the materials, ingredients, design features, heating source, or any other feature of the new products." FDA determined that the information provided is acceptable and that removing (b) (4) from the tobacco filler of the new products does not cause the new products to raise different questions of public health from a chemistry perspective.

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 from a chemistry perspective.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Dilip Venugopal on June 26, 2018.

The final environmental review found that the SE Reports do not provide enough information for an Environmental Assessment for the new products as required in 21 CFR 25.40. Specifically, the environmental review found:

- The applicant did not state if the corresponding predicate products are currently on the market or if they intend to simultaneously market the new and corresponding predicate products.
- The applicant did not provide the current market volumes for the predicate products if these products are currently on the market, or the first-and fifth-year market projections if the intent is to simultaneously market the corresponding predicate products with the new products.

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 only difference in characteristics between the new and predicate tobacco products:

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

The applicant has demonstrated that this difference in characteristics does not cause the new tobacco products to raise different questions of public health. The applicant provided certification statements stating that "there is no other modifications to the materials, ingredients, design features, heating source, or any other feature of the new products." Because this ingredient is removed from the tobacco filler, the toxicity of the new tobacco products is expected to be no worse than the corresponding predicate tobacco products. 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 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, the chemistry review concludes that the difference between the new and corresponding predicate tobacco products is such that the new tobacco products does not raise different questions of public health. I concur with this review 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 products. The status of the predicate products is used to fully assess the environmental impacts of the proposed actions of issuing marketing orders for the new products.
    a) Clarify if the predicate products are currently on the market.
    b) Clarify if you intend to simultaneously market the predicate products after receiving marketing orders for the new products.

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

Table 1: Predicate Product: Projected Market Volumes

Predicate Product		Current Market Volume (# of cigarettes)	First-Year Projected Market Volume (# of cigarettes)	Fifth-Year Projected Market Volume (# of cigarettes)
Name	STN			
Marlboro Menthol Soft Pack	GF1200280			
Marlboro Menthol 100's Box	GF1200140			