

Technical Project Lead (TPL) Review: SE0015290, SE0015291, SE0015295, SE0015297, SE0015301, SE0015303, SE0015310 and SE0015317

SE0015290: Marlboro Special Select (Red Pack) Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None
SE0015291: Marlboro Special Select (Red Pack) 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	99.5 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None
SE0015295: Marlboro Red Label 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None
SE0015297: Marlboro Red Label Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None
SE0015301: Marlboro Menthol Smooth Ice Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	34%
Characterizing Flavor	Menthol

SE0015303: Marlboro Menthol Slate Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	23%
Characterizing Flavor	Menthol
SE0015310: Marlboro Menthol Slate 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter	7.64 mm
Ventilation	17%
Characterizing Flavor	Menthol
SE0015317: Marlboro Black Special Blend Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Attributes of SE Reports	
Applicant	Philip Morris USA Inc.
Report Type	Regular
Product Category	Cigarettes
Product Sub-Category	Combusted, filtered
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Charles Feng -S
Date: 2019.09.18 13:33:24 -04'00'

Charles 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: 2019.09.18 14:13:30 -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:

SE0015290: Marlboro Special Select (Red Pack) Box	
Product Name	Marlboro Special Select (Red Pack) Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None
SE0015291: Marlboro Special Select (Red Pack) 100's Box	
Product Name	Marlboro Special Select (Red Pack) 100's Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	99.5 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None
SE0015295: Marlboro Red Label 100's Box	
Product Name	Marlboro Red Label 100's Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None
SE0015297: Marlboro Red Label Box	
Product Name	Marlboro Red Label Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None

SE0015301: Marlboro Menthol Smooth Ice Box	
Product Name	Marlboro Menthol Gold Pack Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	34%
Characterizing Flavor	Menthol
SE0015303: Marlboro Menthol Slate Box	
Product Name	Marlboro Menthol Slate Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	23%
Characterizing Flavor	Menthol
SE0015310: Marlboro Menthol Slate 100's Box	
Product Name	Marlboro Menthol Slate 100's Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter	7.64 mm
Ventilation	17%
Characterizing Flavor	Menthol
SE0015317: Marlboro Black Special Blend Box	
Product Name	Marlboro Soft Pack
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On June 28, 2019, FDA received eight SE Reports from Altria Client Services LLC, submitted on behalf of Philip Morris USA Inc. FDA issued Acknowledgement letters to the applicant on July 8, 2019.

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 Jessica Kiser on July 7, 2019.

The reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco products in SE0015290, SE0015291, SE0015295, SE0015297, SE0015301, SE0015303, SE0015310 and SE0015317 were previously determined to be substantially equivalent by FDA as shown in the table below. Therefore, the predicate tobacco products are eligible predicate tobacco products.

SE Report	Predicate Tobacco Product	Predicate Tobacco Product Found SE Under:	SE Order Date
SE0015290	Marlboro Special Select (Red Pack) Box	SE0014850	February 13, 2019
SE0015291	Marlboro Special Select (Red Pack) 100's Box	SE0014852	February 13, 2019
SE0015295	Marlboro Red Label 100's Box	SE0014849	February 13, 2019
SE0015297	Marlboro Red Label Box	SE0014851	February 13, 2019
SE0015301	Marlboro Menthol Gold Pack Box	SE0014203	March 1, 2018
SE0015303	Marlboro Menthol Slate Box	SE0014859	February 13, 2019
SE0015310	Marlboro Menthol Slate 100's Box	SE0014858	February 13, 2019
SE0015317	Marlboro Soft Pack	SE0014279	April 19, 2018

The Office of Compliance and Enforcement (OCE) 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 September 3, 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 Karina Zuck on August 9, 2019.

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 differences:

- Addition of (b) (4) mg/cig) in the tipping adhesive
- Replacement of soft pack with hard pack (SE0015317)

The applicant included certification statements indicating that the new and corresponding predicate tobacco products are identical in tobacco blend types, quantities and ingredients, except for (b) (4) mg/cig), that is present in tipping adhesive of the new tobacco products but not in the predicate tobacco products. The amount of (b) (4) included in the new tobacco products is very small, hence unlikely to cause changes in the smoke chemistry. Therefore, from a chemistry perspective, this difference does not cause the new tobacco products to raise different questions of public health.

In SE0015317, the new tobacco product includes a hard pack instead of a soft pack as in the predicate tobacco product. In this case, the difference in the container closure system is not expected to impact smoke chemistry.

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

A toxicology review was completed by Kausar Riaz Ahmed on August 12, 2019.

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 difference:

- Addition of (b) (4) mg/cig) in the tipping adhesive

For all SE Reports, the applicant specified that the product characteristics of the new and predicate products are “*identical*” except for the “*minor difference in tipping adhesive*” caused by the addition of (b) (4) to the tipping adhesive of the new products. The applicant also provided certification statements for all SE Reports indicating that there are no other modifications to materials, ingredients, design features, heating source, or any other feature of the new products other than those specified.

For all SE Reports, (b) (4) is added to the tipping adhesive of the new products as compared to the corresponding predicate products, and it is expected to evaporate during the (b) (4) process. The components of the tipping adhesive are not expected to be burned, volatilized, or be a potential source of thermal degradation resulting in the release of harmful and potentially harmful constituents (HPHCs). 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

An environmental review was completed by Susana Addo Ntim on August 6, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on August 8, 2019. The FONSI was supported by an environmental assessment prepared by FDA on August 8, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Addition of (b) (4) mg/cig) in the tipping adhesive
- Replacement of soft pack with hard pack (SE0015317)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. For all SE Reports, there is an addition of a small quantity of (b) (4) as a solvent in the tipping adhesive. This ingredient is expected to evaporate during the (b) (4) process. Furthermore, tipping adhesive is a part of the non-combusted portion of a cigarette which is not expected to be burned, or to be a potential source of thermal degradation resulting in the formation of HPHCs. For SE0015317, the new tobacco product includes a hard pack compared to a soft pack in the predicate tobacco product. From a chemistry perspective, the difference in container closure system in SE0015317 does not raise different questions of public health because it is not expected to impact smoke chemistry. 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.

The predicate tobacco products were previously determined to be substantially equivalent by FDA under SE0014850, SE0014852, SE0014849, SE0014851, SE0014203, SE0014859, SE0014858 and SE0014279.

Where an applicant supports a showing of SE by comparing the new tobacco product to a tobacco product that FDA previously found SE, in order to issue an SE order, FDA must find that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act).

The predicate tobacco products in SE0015290, SE0015291, SE0015295, SE0015297, SE0015301, SE0015303, SE0015310 and SE0015317 were previously determined to be substantially equivalent by FDA under SE0014850, SE0014852, SE0014849, SE0014851, SE0014203, SE0014859, SE0014858 and SE0014279, respectively. Comparison of the new tobacco products to the grandfathered tobacco products [Marlboro Special Select (Red Pack) Box in SE0014850, Marlboro Special Select (Red Pack) 100's Box in SE0014852, Marlboro Red Label 100's Box in SE0014849, Marlboro Red Label Box in SE0014851, Marlboro Menthol Gold Pack Box in SE0014203, Marlboro Menthol Slate Box in SE0014859, Marlboro Menthol Slate 100's Box in SE0014858, and Marlboro Soft Pack in SE0014279] reveals that the new tobacco products have the following differences in characteristics from

Marlboro Special Select (Red Pack) Box, Marlboro Special Select (Red Pack) 100's Box, Marlboro Red Label 100's Box, Marlboro Red Label Box, Marlboro Menthol Gold Pack Box, Marlboro Menthol Slate Box, Marlboro Menthol Slate 100's Box, and Marlboro Soft Pack, the grandfathered tobacco products:

- Addition of (b) (4) mg/cig) in the tipping adhesive (All SE Reports)
- Addition of the following ingredients to the tipping paper, tipping inks, and ink extender (SE0015290-SE0015291, SE0015295, SE0015297)
 - (b) (4)
 - (b) (4)
 - (b) (4)
 - (b) (4)
 - (b) (4)
 - (b) (4)
 - 211% increase in (b) (4) in the base tipping paper
- Removal of (b) (4) as a flavor ingredient (SE0015301 only)
- Ingredients increased or added to the tipping paper, tipping inks, and tipping ink extenders (SE0015303 and SE0015310)
 - 33-36% increase in (b) (4)
 - 145-156% increase in (b) (4)
 - 185-202% increase in (b) (4)
 - 5% increase in (b) (4)
 - 9% increase in (b) (4) (SE0015310 only)
 - 9% increase in (b) (4) (SE0015310 only)
 - 8-15% increase in (b) (4)
 - 8-9% increase in (b) (4)
 - 9% increase in (b) (4) (SE0015310 only)
 - 232-233% increase in (b) (4)
 - 197-198% increase of (b) (4)
 - Addition of (b) (4)
- Removal of (b) (4) in tipping paper (SE0015317)
- Replacement of soft pack with hard pack (SE0015317)

The differences in characteristics listed above, other than the differences in (b) (4) mg/cig) in tipping adhesive, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0014850, SE0014852, SE0014849, SE0014851, SE0014203, SE0014859, SE0014858 and SE0014279. Therefore, these differences do not cause the new tobacco products in SE0015290, SE0015291, SE0015295, SE0015297, SE0015301, SE0015303, SE0015310 and SE0015317 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in (b) (4) mg/cig) in tipping adhesive between the new tobacco products in SE0015290-SE0015291, SE0015295, SE0015297, SE0015301, SE0015303, SE0015310, and SE0015317 and the corresponding grandfathered tobacco products do not cause the new tobacco products to raise different questions of public health. Therefore, whether comparing the new tobacco products in SE0015290, SE0015291, SE0015295, SE0015297, SE0015301, SE0015303, SE0015310 and SE0015317 to the corresponding predicate or

grandfathered tobacco products, the new tobacco products do not raise different questions of public health.

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 SE0015290, SE0015291, SE0015295, SE0015297, SE0015301, SE0015303, SE0015310 and SE0015317, as identified on the cover page of this review.