

**Technical Project Lead (TPL) Review: SE0015664-SE0015668 and SE0015671-SE0015672**

<b>SE0015664: Marlboro Special Select (Red Pack) Box</b>	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84.0 mm
Diameter <sup>1</sup>	7.89 mm
Ventilation	20%
Characterizing Flavor	None
Additional Property	None
<b>SE0015665: Marlboro Special Select (Gold Pack) Box</b>	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	23%
Characterizing Flavor	None
Additional Property	None
<b>SE0015666: Marlboro Special Select (Red Pack) 100's Box</b>	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	99.5 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None
Additional Property	None
<b>SE0015667: Marlboro Menthol Black Special Blend 100's Box</b>	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.89 mm
Ventilation	16%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 1

<sup>1</sup> The applicant submitted the circumference which allowed for a calculation of diameter.

<b>SE0015668: Marlboro Special Select (Gold Pack) 100's Box</b>	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	99.5 mm
Diameter	7.89 mm
Ventilation	28%
Characterizing Flavor	None
Additional Property	None
<b>SE0015671: Marlboro Menthol Black Special Blend 100's Box</b>	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.89 mm
Ventilation	16%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 2
<b>SE0015672: Marlboro Menthol Black Special Blend 100's Box</b>	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.89 mm
Ventilation	16%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 3
<b>Common Attributes of SE Reports</b>	
Applicant	Philip Morris USA Inc.
Report Type	Regular
Product Category	Cigarettes
Product Sub-Category	Combusted, Filtered
<b>Recommendation</b>	
Issue Substantially Equivalent (SE) orders.	

**Technical Project Lead (TPL):**

Digitally signed by Kenneth Taylor -S  
Date: 2020.04.29 14:08:18 -04'00'

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: 2020.04.29 14:37:42 -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:

<b>SE0015664: Marlboro Special Select (Red Pack) Box</b>	
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
Additional Property	None
<b>SE0015665: Marlboro Special Select (Gold Pack) Box</b>	
Product Name	Marlboro Lights Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.89 mm
Ventilation	23%
Characterizing Flavor	None
Additional Property	None
<b>SE0015666: Marlboro Special Select (Red Pack) 100's Box</b>	
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
Additional Property	None

<b>SE0015667: Marlboro Menthol Black Special Blend 100's Box</b>	
Product Name	Marlboro Menthol Black Special Blend 100's Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.89 mm
Ventilation	16%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 1
<b>SE0015668: Marlboro Special Select (Gold Pack) 100's Box</b>	
Product Name	Marlboro Lights 100's Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99.5 mm
Diameter	7.89 mm
Ventilation	28%
Characterizing Flavor	None
Additional Property	None
<b>SE0015671: Marlboro Menthol Black Special Blend 100's Box</b>	
Product Name	Marlboro Menthol Black Special Blend 100's Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.89 mm
Ventilation	16%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 2
<b>SE0015672: Marlboro Menthol Black Special Blend 100's Box</b>	
Product Name	Marlboro Menthol Black Special Blend 100's Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.89 mm
Ventilation	16%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 3

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

## 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On January 31, 2020, FDA received the SE Reports from Altria Client Services LLC (ALCS) on behalf of Philip Morris USA Inc. (PM USA). FDA issued an Acceptance letter to the applicant on February 10, 2020.

On February 12, 2020, FDA received an amendment (SE0015708) clarifying the name of the predicate tobacco product for SE0015665.

On February 21, 2020, FDA issued a Correction letter for SE0015668 to correct the new tobacco product name. On March 10, 2020, FDA received an amendment (SE0015763) correcting the new tobacco product name.

Product Name	SE Report	Amendments
Marlboro Special Select (Red Pack) Box	SE0015664	None
Marlboro Special Select (Gold Pack) Box	SE0015665	SE0015708
Marlboro Special Select (Red Pack) 100's Box	SE0015666	None
Marlboro Menthol Black Special Blend 100's Box	SE0015667	None
Marlboro Special Select (Gold Pack) 100's Box	SE0015668	SE0015763
Marlboro Menthol Black Special Blend 100's Box	SE0015671	None
Marlboro Menthol Black Special Blend 100's Box	SE0015672	None

## 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 Ester Hatton on February 10, 2020.

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 in SE0015665 and SE0015668 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 March 11, 2020, 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.

The predicate tobacco products in SE0015664, SE0015666, SE0015667, SE0015671 and SE0015672 were determined to be substantially equivalent by FDA as shown in the table below. Therefore, these products are eligible predicate tobacco products.

SE Report	Predicate Tobacco Product	Predicate Tobacco Product Found SE Under:	Date
SE0015664	Marlboro Special Select (Red Pack) Box	SE0014850	February 13, 2019
SE0015666	Marlboro Special Select (Red Pack) 100's Box	SE0014852	February 13, 2019
SE0015667	Marlboro Menthol Black Special Blend 100's Box	SE0014889	January 15, 2019
SE0015671	Marlboro Menthol Black Special Blend 100's Box	SE0014905	January 15, 2019
SE0015672	Marlboro Menthol Black Special Blend 100's Box	SE0014908	January 15, 2019

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 reviews, dated April 9, 2020, conclude 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 An T. Vu on March 16, 2020.

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:

##### SE0015664, SE0015665

- Cigarette seam adhesive:
  - Decrease in <sup>(b) (4)</sup> [REDACTED] mg/cigarette (cig), ↓ 48%)
  - Increase in <sup>(b) (4)</sup> [REDACTED] mg/cig, ↑ 379%)
- Tipping adhesive:
  - Addition of <sup>(b) (4)</sup> [REDACTED] mg/cig)

##### SE0015666, SE0015668

- Cigarette seam adhesive:
  - Decrease in <sup>(b) (4)</sup> [REDACTED] mg/cig, ↓ 48%)
  - Increase in <sup>(b) (4)</sup> [REDACTED] mg/cig, ↑ 377%)
- Tipping adhesive:
  - Addition of <sup>(b) (4)</sup> [REDACTED] mg/cig)

**SE0015667, SE0015671, SE0015672**

- Cigarette seam adhesive:
  - Decrease in (b) (4) mg/cig, ↓ 47%)
  - Increase in (b) (4) mg/cig, ↑ 367%)
- Tipping adhesive:
  - Addition of (b) (4) mg/cig)

The new tobacco products have key ingredient differences in the cigarette seam adhesive and tipping paper adhesive. In the cigarette seam adhesive, (b) (4) is decreased and (b) (4) is increased. The non-intense International Organization of Standards (ISO) and Canadian Intense (CI) mainstream machine smoking regimen yields of tar, nicotine, carbon monoxide, acetaldehyde, acrolein, acrylonitrile, ammonia, benzene, benzo- $\alpha$ -pyrene, 1,3-butadiene, crotonaldehyde, formaldehyde, isoprene, NNK, NNN, and toluene are analytically equivalent for the new and corresponding predicate tobacco products. Therefore, the ingredient changes in cigarette seam adhesives are not a concern. The tipping paper adhesive is a non-combusted/non-consumed component, so the addition of (b) (4) in the new tobacco products does not cause apparent concerns.

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. ENGINEERING**

An engineering review was completed by Jimin P. Kim on March 16, 2020.

The final 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, 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 related to product engineering.

**4.3. TOXICOLOGY**

A toxicology review was completed by Chad Brocker on March 20, 2020.

The final 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 differences:

**All SE Reports**

- Ingredients added to cigarette seam adhesive
  - (b) (4) mg/cig)
  - (b) (4) mg/cig)
  - (b) (4) mg/cig)
- Ingredients added to tipping adhesive
  - (b) (4) mg/cig)

The cigarette seam adhesive ingredients (b) (4) are added at levels that do not raise toxicological concerns in the new tobacco products. However, (b) (4) may impact yields of harmful and potentially harmful constituents (HPHCs) such as acetaldehyde, acrolein, benzene, and formaldehyde. The mainstream smoke yields of these HPHCs are determined in the chemistry review to be analytically equivalent between the new and corresponding predicate tobacco products for both non-intense ISO and CI smoking regimens. These results suggest that the additions of (b) (4) in the cigarette seam adhesive of the new tobacco products do not adversely affect HPHC smoke yields. The addition of (b) (4) to the tipping adhesive in the new tobacco products is also not anticipated to affect smoke HPHCs as it is not combusted during product use.

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 Bria J. Martin on March 11, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on March 13, 2020. The FONSI was supported by an environmental assessment prepared by FDA on March 13, 2020.

**6. CONCLUSION AND RECOMMENDATION**

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

**SE0015664, SE0015665**

- Cigarette seam adhesive:
  - Decrease in (b) (4) mg/cig, ↓ 48%)
  - Increase in (b) (4) mg/cig, ↑ 379%)
  - Addition of (b) (4)

- Tipping adhesive:
  - Addition of (b) (4) mg/cig)

**SE0015666, SE0015668**

- Cigarette seam adhesive:
  - Decrease in (b) (4) mg/cig, ↓ 48%)
  - Increase in (b) (4) mg/cig, ↑ 377%)
  - Addition of (b) (4)
- Tipping adhesive:
  - Addition of (b) (4) mg/cig)

**SE0015667, SE0015671, SE0015672**

- Cigarette seam adhesive:
  - Decrease in (b) (4) mg/cig, ↓ 47%)
  - Increase in (b) (4) mg/cig, ↑ 367%)
  - Addition of (b) (4)
- Tipping adhesive:
  - Addition of (b) (4) mg/cig)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The new tobacco products have ingredient differences in the cigarette seam adhesive and tipping paper adhesive, some of which may affect HPHC yields ((b) (4)). The ingredient differences are at amounts that do not present toxicological concerns. Additionally, the non-intense ISO and CI mainstream machine smoking regimen yields of tar, nicotine, carbon monoxide, acetaldehyde, acrolein, acrylonitrile, ammonia, benzene, benzo- $\alpha$ -pyrene, 1,3-butadiene, crotonaldehyde, formaldehyde, isoprene, NNK, NNN, and toluene are analytically equivalent for the new and corresponding predicate tobacco products; which demonstrate that the ingredient differences do not significantly affect smoke HPHCs. Also, since the tipping paper adhesive is a non-combusted/consumed component, the addition of (b) (4) in the new tobacco products does not cause concerns. 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 in SE0015665 and SE0015668 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 predicate tobacco products in SE0015664, SE0015666, SE0015667, SE0015671 and SE0015672 were previously determined to be substantially equivalent by FDA in SE0014850, SE0014852, SE0014889, SE0014905, and SE0014908, respectively.

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 SE0015664, SE0015666, SE0015667, SE0015671 and SE0015672 were previously determined to be substantially equivalent by FDA under SE0014850, SE0014852, SE0014889, SE0014905, and SE0014908, respectively. Comparison of the new tobacco products to the grandfathered products (Marlboro Medium Soft Pack in SE0014850, Marlboro Medium 100's Soft Pack in SE0014852 and Marlboro Menthol 100's Box in SE0014889, SE0014905 and SE0014908) reveals that the new tobacco products have the following differences in characteristics from Marlboro Medium Soft Pack, Marlboro Medium 100's Soft Pack and Marlboro Menthol 100's Box, the grandfathered tobacco products:

**SE0015664**

- Cigarette seam adhesive:
  - Decrease in (b) (4) mg/cig, ↓ 48%)
  - Increase in amount of (b) (4) mg/cig, ↑ 379%)
- Tipping adhesive:
  - Addition of (b) (4) mg/cig)
- Base tipping paper:
  - Decrease in (b) (4) mg/cig, ↓ 64%)
  - Increase in (b) (4) mg/cig, ↑ 211%)
- Tipping ink:
  - Decrease in (b) (4) mg/cig, ↓ 24%)

**SE0015666**

- Cigarette seam adhesive:
  - Decrease in (b) (4) mg/cig, ↓ 48%)
  - Increase in amount of (b) (4) mg/cig, ↑ 377%)
- Tipping adhesive:
  - Addition of (b) (4) mg/cig)
- Base tipping paper:
  - Decrease in (b) (4) mg/cig, ↓ 64%)
  - Increase in (b) (4) mg/cig, ↑ 211%)
- Tipping ink:
  - Decrease in (b) (4) mg/cig, ↓ 26%)

**SE0015667**

- Cigarette seam adhesive:
  - Decrease in (b) (4) mg/cig, ↓ 47%)
  - Increase in amount of (b) (4) mg/cig, ↑ 367%)
- Tipping adhesive:
  - Addition of (b) (4) mg/cig)
- Base tipping paper:
  - Addition of (b) (4) mg/cig)
  - Removal of (b) (4) mg/cig)
- Tipping ink:
  - Decrease in (b) (4) mg/cig, ↓ 45%)
- Tobacco additives:
  - Removal of (b) (4) mg/cig)

**SE0015671**

- Cigarette seam adhesive:
  - Decrease in (b) (4) mg/cig, ↓ 47%)
  - Increase in amount of (b) (4) mg/cig, ↑ 367%)
- Tipping adhesive:
  - Addition of (b) (4) mg/cig)
- Base tipping paper:
  - Addition of (b) (4) mg/cig)
  - Decrease in (b) (4) mg/cig, ↓ 9%)
  - Decrease in (b) (4) mg/cig, ↓ 5%)
  - Addition of (b) (4) mg/cig)
  - Removal of (b) (4) mg/cig)
- Tipping ink
  - Decrease in (b) (4) mg/cig, ↓ 45%)
- Tobacco additives:
  - Removal of (b) (4) mg/cig)

**SE0015672**

- Cigarette seam adhesive:
  - Decrease in (b) (4) mg/cig, ↓ 47%)
  - Increase in amount of (b) (4) mg/cig, ↑ 367%)
- Tipping adhesive:
  - Addition of (b) (4) mg/cig)
- Base tipping paper:
  - Decrease in (b) (4) mg/cig, ↓ 34%)
- Tipping ink:
  - Decrease in (b) (4) mg/cig, ↓ 45%)
- Tobacco additives:
  - Removal of (b) (4) mg/cig)

The differences in characteristics listed above, other than the differences in base tipping paper and tipping ink, are the same differences in characteristics identified for the new and predicate tobacco products in SE0015664, SE0015666, SE0015667, SE0015671 and SE0015672. Therefore, these differences do not cause the new tobacco products in SE0015664, SE0015666, SE0015667, SE0015671 and SE0015672 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in base tipping paper and tipping ink between the new tobacco products in SE0015664, SE0015666, SE0015667, SE0015671 and SE0015672 and the 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 SE0015664, SE0015666, SE0015667, SE0015671 and SE0015672 to the 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 SE0015664, SE0015665, SE0015666, SE0015667, SE0015668, SE0015671, and SE0015672, as identified on the cover page of this review.