

Technical Project Lead (TPL) Review: SE0015307, SE0015311, SE0015312, SE0015319, SE0015320, SE0015322, SE0015324, SE0015327, and SE0015329

SE0015307: Marlboro Black Special Blend 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	99 millimeters (mm)
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	Tipping Paper 3
SE0015311: Marlboro Black Special Blend 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	Tipping Paper 2
SE0015312: Marlboro Black Special Blend 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	Tipping Paper 1
SE0015319: Chesterfield Menthol Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 3

SE0015320: Chesterfield Menthol Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 1
SE0015322: Chesterfield Menthol Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 2
SE0015324: Chesterfield Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	None
Additional Property	Tipping paper 3
SE0015327: Chesterfield Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	None
Additional Property	Tipping Paper 1
SE0015329: Chesterfield Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	None

Additional Property	Tipping Paper 2
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):

Jeannie H. Jeong-im -S Digitally signed by Jeannie H. Jeong-im -S Date: 2019.09.25 08:53:33 -04'00'
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Jeannie Jeong-Im, 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: 2019.09.25 16:55:56 -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:

SE0015307: Marlboro Black Special Blend 100's Box	
Product Name	Marlboro Black Special Blend 100's Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	Tipping Paper 3
SE0015311: Marlboro Black Special Blend 100's Box	
Product Name	Marlboro Black Special Blend 100's Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	Tipping Paper 2
SE0015312: Marlboro Black Special Blend 100's Box	
Product Name	Marlboro Black Special Blend 100's Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	Tipping Paper 1
SE0015319: Chesterfield Menthol Box	
Product Name	Chesterfield Menthol Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol

Additional Property	N/A
SE0015320: Chesterfield Menthol Box	
Product Name	Chesterfield Menthol Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 1
SE0015322: Chesterfield Menthol Box	
Product Name	Chesterfield Menthol Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping paper 2
SE0015324: Chesterfield Box	
Product Name	Chesterfield Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	None
Additional Property	N/A
SE0015327: Chesterfield Box	
Product Name	Chesterfield Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	None
Additional Property	Tipping Paper 1

SE0015329 : Chesterfield Box	
Product Name	Chesterfield Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	None
Additional Property	Tipping Paper 2

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 nine SE Reports from Altria Client Services LLC on behalf of Philip Morris USA Inc. FDA issued an Acknowledgment letter 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 Maria Suarez on July 7, 2019.

The reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco products in SE0015307, SE0015311, SE0015312, SE0015319, SE0015320, SE0015322, SE0015324, SE0015327, and SE0015329 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:	Date
SE0015307	Marlboro Black Special Blend 100's Box	SE0014890	January 9, 2019
SE0015311	Marlboro Black Special Blend 100's Box	SE0014888	January 9, 2019
SE0015312	Marlboro Black Special Blend 100's Box	SE0014886	January 9, 2019
SE0015319	Chesterfield Menthol Box	SE0014816	September 27, 2018
SE0015320	Chesterfield Menthol Box	SE0014891	January 15, 2019

SE0015322	Chesterfield Menthol Box	SE0014906	January 15, 2019
SE0015324	Chesterfield Box	SE0014815	September 27, 2018
SE0015327	Chesterfield Box	SE0014892	January 15, 2019
SE0015329	Chesterfield Box	SE0014907	January 15, 2019

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 dated 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 Megan L. Mekoli on August 14, 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 difference:

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

The tipping paper adhesive is not a part of the cigarette that is combusted during normal cigarette use, and not expected to contribute to HPHC smoke yields. Therefore, the modification to this component does not cause the new tobacco products to raise different questions of public health with regard to chemistry.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on August 16, 2019. The FONSI was supported by an environmental assessment prepared by FDA on August 16, 2019.

6. CONCLUSION AND RECOMMENDATION

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

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

The applicant has demonstrated that this difference in characteristics does not cause the new tobacco products to raise different questions of public health. The (b) (4) is added to the tipping paper adhesive. The tipping paper adhesive is not a part of the cigarette that is combusted during normal cigarette use, and not expected to contribute to HPHC smoke yields.

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 were previously determined to be substantially equivalent by FDA under SE0014815, SE0014816, SE0014886, SE0014888, SE0014890, SE0014891, SE0014892, SE0014906, and SE0014907.

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 SE0015307, SE0015311, SE0015312, SE0015319, SE0015320, SE0015322, SE0015324, SE0015327, and SE0015329 were previously determined to be substantially equivalent by FDA under SE0014890, SE0014888, SE0014886, SE0014816, SE0014891, SE0014906, SE0014815, SE0014892 and SE0014907, respectively. Comparison of the new tobacco products to the corresponding grandfathered products¹ reveals that the new tobacco products have the following differences in characteristics from Basic Full Flavor Box [GF1200071], Basic Menthol Box [GF1200077], Marlboro 100's Soft Pack [GF1200272]:

Container Closure System

SE0015307, SE0015311, SE0015312

- The new tobacco product container closure system is identified as a box whereas that of the corresponding predicate tobacco product is identified as a soft pack

Base Tipping Paper

SE0015307

- 2% (b) (4) cigarette) lower (b) (4)

SE0015322 and SE0015329

- Addition of (b) (4) /cigarette of (b) (4)
- Deletion of (b) (4) /cigarette of (b) (4)

SE0015307, SE0015322, and SE0015329

- Addition of (b) (4) /cigarette of (b) (4)
- Deletion of (b) (4) /cigarette of (b) (4)
- Decrease of 34 – 45% (b) (4) /cigarette) of (b) (4)
- Increase of 59 – 1627% (b) (4) /cigarette) of (b) (4)

¹ Basic Full Flavor Box [GF1200071] in SE0014815, Basic Menthol Box [GF1200077] in SE0014816, Marlboro 100's Soft Pack [GF1200272] in SE0014886, Marlboro 100's Soft Pack [GF1200272] in SE0014888, Marlboro 100's Soft Pack [GF1200272] in SE0014890, Basic Menthol Box [GF1200077] in SE0014891, Basic Full Flavor Box [GF1200071] in SE0014892, Basic Menthol Box [GF1200077] in SE0014906, and Basic Full Flavor Box [GF1200071] in SE0014907

SE0015312, SE0015319, and SE0015324

- Addition of (b) (4) /cigarette of (b) (4)
- Deletion of (b) (4) /cigarette of (b) (4)
- Decrease of 2 – 90% (b) (4) cigarette) of (b) (4)
- Increase of 4% (b) (4) /cigarette) of (b) (4)

SE0015311, SE0015320, and SE0015327

- Addition of (b) (4) /cigarette of (b) (4)
- Deletion of (b) (4) /cigarette of (b) (4)
- Decrease of 5 – 9% (b) (4) /cigarette) of (b) (4)

Brown Ink

SE0015307, SE0015311, and SE0015312

- Addition of (b) (4) cigarette of (b) (4)
- Deletion of (b) (4) /cigarette of (b) (4)
- Decrease of 28 – 45% (b) (4) /cigarette) of (b) (4)
- Increase of 268% (b) (4) cigarette) and 279% (b) (4) /cigarette) of (b) (4) respectively

SE0015319, SE0015320, SE0015322, SE0015324, SE0015327, and SE0015329

- Addition of (b) (4) /cigarette of (b) (4)
- Deletion of (b) (4) /cigarette of (b) (4)
- Decrease of 20 – 46% (b) (4) cigarette) of (b) (4)
- Increase of 257– 309% (b) (4) /cigarette) of (b) (4)

Gold Ink

SE0015307, SE0015311, and SE0015312

- Addition of (b) (4) /cigarette of (b) (4)
- Deletion of (b) (4) /cigarette of (b) (4)
- Decrease of 14 – 99% (b) (4) /cigarette) of (b) (4)

Tipping Ink Extender

SE0015307 (1), SE0015311 (1), and SE0015312 (1), SE0015319, SE0015320, SE0015322, SE0015324, SE0015327, and SE0015329

- Addition of (b) (4) /cigarette of (b) (4)
- Deletion of (b) (4) /cigarette of (b) (4)
- Decrease of 14 – 29% (b) (4) /cigarette) of (b) (4)

SE0015307 (2), SE0015311 (2), and SE0015312 (2)

- Addition of (b) (4) /cigarette of (b) (4)
- Deletion of (b) (4) /cigarette of (b) (4)
- Decrease of 54 – 97% (b) (4) /cigarette) of (b) (4)
- Increase of 97% (b) (4) /cigarette) of (b) (4)

Tipping Paper Adhesive

All SE Reports

- Addition of (b) (4) /cigarette of (b) (4)

The differences in characteristics listed above, other than the differences in tipping paper adhesive, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0015307, SE0015311, SE0015312, SE0015319, SE0015320, SE0015322, SE0015324, SE0015327, and SE0015329. Therefore, these differences do not cause the new tobacco products in SE0015307, SE0015311, SE0015312, SE0015319, SE0015320, SE0015322, SE0015324, SE0015327, and SE0015329 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in base tipping paper, inks, tipping paper extender, and tipping paper adhesive between the new tobacco products in SE0015307, SE0015311, SE0015312, SE0015319, SE0015320, SE0015322, SE0015324, SE0015327, and SE0015329 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 SE0015307, SE0015311, SE0015312, SE0015319, SE0015320, SE0015322, SE0015324, SE0015327, and SE0015329 to the predicate of 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 SE0015307, SE0015311, SE0015312, SE0015319, SE0015320, SE0015322, SE0015324, SE0015327, and SE0015329, as identified on the cover page of this review.