

Technical Project Lead (TPL) Review: SE0015507, SE0015508, and SE0015509

SE0015507: 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
SE0015508: Chesterfield Blue Pack 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98.5 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None
SE0015509: Marlboro Red Label Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None
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: 2019.12.11 18:40:31 -05'00'

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: 2019.12.12 09:41:35 -05'00'

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:

SE0015507: 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
SE0015508: Chesterfield Blue Pack 100's Box	
Product Name	Chesterfield Blue Pack 100's Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98.5 mm
Diameter	7.89 mm
Ventilation	20%
Characterizing Flavor	None
SE0015509: 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

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On September 20, 2019, FDA received the SE Reports from Altria Client Services (ALCS) on behalf of Philip Morris USA Inc. FDA issued an Acceptance letter on September 27, 2019, for all the SE Reports.

Product Name	SE Report
Marlboro Special Select (Red Pack) 100's Box	SE0015507
Chesterfield Blue Pack 100's Box	SE0015508
Marlboro Red Label Box	SE0015509

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 September 27, 2019.

The reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco products in SE0015507, SE0015508, and SE0015509 were determined to be substantially equivalent by FDA under SE0014852, SE0015058, and SE0014851, respectively. Therefore, these products 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 December 4, 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 Jiu Ai on October 31, 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:

SE0015507

- Composition changes in cigarette paper
 - o 13.7% increase in (b) (4)
 - o 105% increase in (b) (4)
 - o 104% increase in (b) (4)
 - o 13.9% decrease in (b) (4)
 - o 19.6% decrease in (b) (4)
- Composition changes in FSC bands
 - o Addition of (b) (4)
 - o 600% increase in (b) (4)
 - o 20.5% decrease in (b) (4)
- Composition changes in tipping adhesive
 - o Addition of (b) (4)

SE0015508

- Composition changes in cigarette paper
 - o 13.1% increase in (b) (4)
 - o 100% increase in (b) (4)
 - o 100% increase in (b) (4)
 - o 16.1% decrease in (b) (4)
 - o 21.6% decrease in (b) (4)
- Composition changes in FSC bands
 - o Addition of (b) (4)
 - o 335% increase in (b) (4)
 - o 30% decrease in (b) (4)
- Composition changes in tipping adhesive
 - o Addition of (b) (4)

SE0015509

- Composition changes in cigarette paper
 - o 2.7% increase in (b) (4)
 - o 95.9% increase in (b) (4)
 - o 95.0% increase in (b) (4)
 - o 0.2% increase in (b) (4)
 - o 24% decrease in (b) (4)
- Composition changes in FSC bands
 - o Addition of (b) (4)
 - o 475% increase in (b) (4)
 - o 33.9% decrease in (b) (4)
- Composition changes in tipping adhesive
 - o Addition of (b) (4)

The applicant submitted smoke yields of TNCO, carbonyls, volatile organics, benzo- α -pyrene, NNK, NNN and puff counts using both ISO and Canadian Intense (CI) smoking regimens for the new and corresponding predicate tobacco products, which were determined to be analytically

equivalent.¹ Therefore, the cigarette paper and FSC band differences do not cause the new tobacco products to raise different questions of public health. Also, (b) (4) is added to the tipping adhesive of the new tobacco products at an amount of (b) (4). However, this quantity is less than 0.1% of the total cigarette weight, and the tipping adhesive is not combusted during smoking. Smoke chemistry will not be measurably affected by this change.

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 Morgan E. Lee on October 31, 2019.

The engineering review concludes that the new tobacco products have different characteristics related to product engineering 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

- 0.5-1% differences in cigarette paper band space

SE0015508

- 4.6% increase in cigarette paper band width

The differences in cigarette paper band space and bandwidth between the new and the corresponding predicate tobacco are anticipated to be too small to affect 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 an engineering perspective.

4.3. TOXICOLOGY

A toxicology review was completed by Mamata De on November 6, 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

¹ Determined using a Two One-Sided T-test (TOST) which is a statistical tool that calculates important analytical differences using the Horwitz-Thompson equation. The mean range of a TOST analysis is a measure of statistical probability that differences in a mean range of tested values are analytically significant. An equivalence margin at a 75% confidence interval reduces the number of inconclusive results, which default to be considered as not analytically equivalent.

differences do not cause the new tobacco products to raise different questions of public health. The review identified the following differences:

SE0015507

- Addition of (b) (4)
- 104% increase in (b) (4)
- 600% increase in (b) (4)
- 89.2% increase in (b) (4)

SE0015508

- Addition of (b) (4)
- 100% increase in (b) (4)
- 335% increase in (b) (4)
- Addition of (b) (4)

SE0015509

- 2.72% increase in (b) (4)
- 130% increase in (b) (4)
- Addition of (b) (4)
- Addition of (b) (4)

The mainstream smoke yields of acetaldehyde, formaldehyde, acrolein, carbon monoxide, benzo- α -pyrene are analytically equivalent between the new and corresponding predicate tobacco products, demonstrating that the differences in (b) (4) do not cause the new tobacco products to raise different questions of public health. Also, the new tobacco products have lower puff counts than the corresponding predicate tobacco products, which indicates a higher burn rate and concomitant reduction in exposure to smoke toxicants. Thus, the differences in the burn modifiers (b) (4) are a favorable change in the new tobacco products. Finally, the addition of (b) (4) to the tipping adhesive is not a concern because it is in a non-combusted component of the cigarette and is not anticipated to affect smoke chemistry or have direct oral or dermal contact.

Therefore, the review concludes that the applicant did not demonstrate that 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 Dilip Venugopal on November 14, 2019. A finding of no significant impact (FONSI) was signed by Kimberly Benson on December 10, 2019. The FONSI was supported by an environmental assessment prepared by FDA on December 9, 2019.

² The toxicology review incorrectly notes that (b) (4) is added. (b) (4) is also referred to simply as (b) (4). The applicant uses both terms interchangeably for the new and corresponding predicate tobacco products. The chemistry review correctly indicated that (b) (4) is decreased, not added, in the new tobacco products.

6. CONCLUSION AND RECOMMENDATION

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

SE0015507

- Composition changes in cigarette paper
 - o 13.7% increase in (b) (4)
 - o 105% increase in (b) (4)
 - o 104% increase in (b) (4)
 - o 13.9% decrease in (b) (4)
 - o 19.6% decrease in (b) (4)
- Composition changes in FSC bands
 - o Addition of (b) (4)
 - o 600% increase in (b) (4)
 - o 20.5% decrease in (b) (4)
- Composition changes in tipping adhesive
 - o Addition of (b) (4)
- 0.5% increase in cigarette paper band space

SE0015508

- Composition changes in cigarette paper
 - o 13.1% increase in (b) (4)
 - o 100% increase in (b) (4)
 - o 100% increase in (b) (4)
 - o 16.1% decrease in (b) (4)
 - o 21.6% decrease in (b) (4)
- Composition changes in FSC bands
 - o Addition of (b) (4)
 - o 335% increase in (b) (4)
 - o 30% decrease in (b) (4)
- Composition changes in tipping adhesive
 - o Addition of (b) (4)
- 4.6% increase in cigarette paper band width
- 1% decrease in cigarette paper band space

SE0015509

- Composition changes in cigarette paper
 - o 2.7% increase in (b) (4)
 - o 95.9% increase in (b) (4)
 - o 95.0% increase in (b) (4)
 - o 0.2% increase in (b) (4)
 - o 24% decrease in (b) (4)
- Composition changes in FSC bands
 - o Addition of (b) (4)
 - o 475% increase in (b) (4)
 - o 33.9% decrease in (b) (4)
- Composition changes in tipping adhesive

- o Addition of (b) (4)
- 0.5% increase in cigarette paper band space

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 and design differences to the cigarette paper, FSC band material, and tipping adhesive. The increases in (b) (4) (cigarette paper) and addition of (b) (4) (FSC band) can produce HPHCs such as acetaldehyde, formaldehyde, and acrolein as pyrolysis products. However, smoke yields of TNCO, carbonyls, volatile organics, benzo- α -pyrene, NNK, NNN and puff counts using both ISO and Canadian Intense (CI) smoking regimens are analytically equivalent for the new and corresponding predicate tobacco products. Therefore, the cigarette paper and FSC band differences do not cause the new tobacco products to raise different questions of public health. Tipping adhesive is a noncombusted component, so the addition of (b) (4) is not anticipated to affect smoke chemistry. Finally, the changes in the cigarette paper band space and band width are not anticipated to affect smoke chemistry, which is also supported by the analytically equivalent HPHC smoke data. 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 were previously determined to be substantially equivalent by FDA under SE0014852, SE0015058 and SE0014851.

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 SE0015507, SE0015508, and SE0015509 were previously determined to be substantially equivalent by FDA under SE0014852, SE0015058 and SE0014851, respectively. Comparison of the new tobacco products to the grandfathered products Marlboro Medium 100's Soft Pack in SE0015507, Basic Lights 100s in SE0015508 and Marlboro Medium in SE0015509) reveals that the new tobacco products have the following differences in characteristics from Marlboro Medium 100's Soft Pack, Basic Lights 100s, and Marlboro Medium, the grandfathered tobacco products:

SE0015507

- Composition changes in cigarette paper
 - o 13.7% increase in (b) (4)
 - o 105% increase in (b) (4)
 - o 104% increase in (b) (4)
 - o 13.9% decrease in (b) (4)
 - o 19.6% decrease in (b) (4)
- Composition changes in FSC bands
 - o Addition of (b) (4)
 - o 600% increase in (b) (4)
 - o 20.5% decrease in (b) (4)
- Composition changes in tipping adhesive
 - o Addition of (b) (4)

- Composition changes in tipping paper
 - 211% increase in (b) (4)
 - 64% decrease in (b) (4)
- Composition changes in tipping ink and extender
 - 26% decrease in (b) (4)
 - Removal of (b) (4)
- 0.5% increase in cigarette paper band space

SE0015508

- Composition changes in cigarette paper
 - 13.1% increase in (b) (4)
 - 100% increase in (b) (4)
 - 100% increase in (b) (4)
 - 16.1% decrease in (b) (4)
 - 21.6% decrease in (b) (4)
- Composition changes in FSC bands
 - Addition of (b) (4)
 - 335% increase in (b) (4)
 - 30% decrease in (b) (4)
- Composition changes in tipping adhesive
 - Addition of (b) (4)
- Composition changes in tipping paper
 - 211% increase in (b) (4)
 - 64% decrease in (b) (4)
- Composition changes in tipping ink and extender
 - Addition of (b) (4)
 - Removal of (b) (4)
 - Addition of ink extender
 - Removal of ink extender 1 and ink extender 2
 - Addition of lip release
- 4.6% increase in cigarette paper band width
- 1% decrease om cigarette paper band space

SE0015509

- Composition changes in cigarette paper
 - 2.7% increase in (b) (4)
 - 95.9% increase in (b) (4)
 - 95.0% increase in (b) (4)
 - 0.2% increase in (b) (4)
 - 24% decrease in (b) (4)
- Composition changes in FSC bands
 - Addition of (b) (4)
 - 475% increase in (b) (4)
 - 33.9% decrease in (b) (4)
- Composition changes in tipping adhesive
 - Addition of (b) (4)
- Composition changes in tipping paper
 - 211% increase in (b) (4)
 - 64% decrease in (b) (4)

- Composition changes in tipping ink and extender
 - 24% decrease in (b) (4)
 - Removal of (b) (4)
- 0.5% increase in cigarette paper band space

The differences in characteristics listed above, other than the differences in composition changes in cigarette paper, FSC bands, tipping paper adhesive, and band space and band width, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0014852, SE0015058 and SE0014851. Therefore, these differences do not cause the new tobacco products in SE0015507, SE0015508, and SE0015509 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in composition changes in cigarette paper, FSC bands, tipping paper adhesive, and band space and band width between the new tobacco products in SE0015507, SE0015508, and SE0015509 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 SE0015507, SE0015508, and SE0015509 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 an SE order letter be issued.

FDA examined the environmental effects of finding these new tobacco products substantially equivalent and made a finding of no significant impact.

An SE order letter should be issued for the new tobacco products in SE0015507, SE0015508, and SE0015509, as identified on the cover page of this review.