Technical Project Lead (TPL) Review: SE0015539 - SE0015541

SE0015539: Marlboro Black Special Blend 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter[1]	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	Tipping paper 1
SE0015540: Marlboro Black Special Blend 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter[1]	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	Tipping paper 2
SE0015541: Marlboro Black Special Blend 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter[1]	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	Tipping paper 3
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.	

[1] The applicant submitted the circumference which allowed for a calculation of diameter.

Technical Project Lead (TPL):

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Date: 2020.06.18 15:28:04 -04'00'

Samantha Spindel, Ph.D., M.Eng.
CDR, US Public Health Service
Engineering 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: 2020.06.18 15:34:19 -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:

SE0015539: 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[1]	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	Tipping paper 1
SE0015540: 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[1]	7.89 mm
Ventilation	15%
Characterizing Flavor	None
Additional Property	Tipping paper 2
SE0015541: 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[1]	7.89 mm
Ventilation	15%
Characterizing Flavor	None
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 October 22, 2019, FDA received three SE Reports from Altria Client Services LLC, on behalf of Philip Morris USA Inc. FDA issued an Acceptance letter to the applicant on October 28, 2019. On January 15, 2020, FDA issued a Deficiency letter to the applicant. On March 31, 2020, FDA received an amendment containing a response to the Deficiency letter (SE0015794).

Product Name	SE Report	Amendments
Marlboro Black Special Blend 100's Box	SE0015539	SE0015794
Marlboro Black Special Blend 100's Box	SE0015540	
Marlboro Black Special Blend 100's Box	SE0015541	

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 Ebony Griffin on October 28, 2019.

The reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco products in SE0015539, SE0015540, and SE0015541 were determined to be substantially equivalent by FDA under SE0014886, SE0014888, and SE0014890, respectively. Therefore, the predicate tobacco products are eligible predicate tobacco products.

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 section910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated May 27, 2020, 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 reviews were completed by Jason Hsieh on December 19, 2019, and on May 15, 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:

- Cigarette Paper Ingredients
  - Addition of (b) (4) mg/cig); removal of (b) (4) mg/cig)
- Cigarette Band Ingredients
  - Addition of (b) (4) mg/cig); addition of (b) (4) mg/cig); removal of (b) (4) mg/cig)
- Monogram Ink Ingredients
  - Removal of (b) (4) mg/cig)
- Tipping Adhesive
  - Addition of (b) (4) mg/cig)

The applicant certified that the characteristics of the new and predicate tobacco products were identical in materials, ingredients, design features, heating source, or any other feature of the new product, except for the non-tobacco ingredients such as cigarette paper (including the cigarette band), monogram ink, and tipping adhesive. There are many ingredient differences in new and corresponding tobacco products. In addition, an issue regarding the changes in cigarette paper band porosity (i.e., band permeability) was identified, which was deferred to Chemistry from Engineering. The applicant submitted Harmful and Potentially Harmful Constituent (HPHC) data for only new and predicate products in SE0015539. Because the tipping paper is not combusted, volatilized, or otherwise released during regular cigarette consumption (and because the only differences between the new product in SE0015539 and the new tobacco products in SE0015540 and SE0015541 are in the tipping paper), a representative HPHC data set for SE0015539 is acceptable to extrapolate the HPHC smoke yields of the new and corresponding predicate tobacco products in SE0015540 and SE0015541.

The characteristics between the current new products and corresponding predicate products are identical except for minor differences in the combusted portion; however, all tar, nicotine, and carbon monoxide (TNCO) and HPHC yields from International Organization of Standardization (ISO) and Canadian Intense (CI) smoking regimens were analytically equivalent via Two One-Sided T-Tests (TOST) analysis. This demonstrates that these differences (i.e., changes in band permeability, changes in cigarette paper ingredients, changes in monogram ink ingredients, and changes in cigarette band ingredients) between the new and predicate tobacco products do not cause the new tobacco products to raise different questions of public health, from a chemistry perspective.

Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco product to raise different questions of public health from a chemistry perspective.

4.2. ENGINEERING

Engineering reviews were completed by Nashaat Rasheed on January 09, 2020 and by Mohammad M. Ali on May 16, 2020.

The final 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:

- Cigarette paper band porosity test data (CU): ↓41% (the target specifications and range limits are identical)

For all SE Reports, the applicant provides a Certification Statement regarding overall cigarette length, overall cigarette diameter, tobacco rod density, tobacco moisture, tobacco cut size, filter pressure drop, filter length, filter density, filter ventilation, filter total denier, filter denier per filament, and tipping paper length that they are the same for the new and corresponding predicate tobacco products. The cigarette paper band porosity target specification and range limits for the new and corresponding predicate tobacco products are identical. However, the test data average value for the new tobacco products is 41% lower (4.83 CU) than the test data average of the corresponding predicate tobacco products (8.19 CU). Although the applicant demonstrated measured test data average values for the new and the corresponding predicate products fall within the band porosity (i.e., band permeability) range limits, an average test data value for the new tobacco products that is 41% lower than the test data average of the corresponding predicate tobacco products may lead to an increase in TNCO smoke yields. Therefore, the evaluation of the TNCO for the new and corresponding predicate products for all SE Reports is deferred to chemistry.

Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco product to raise different questions of public health from an engineering perspective.

4.3. TOXICOLOGY

A toxicology review was completed by Kamau O. Peters on December 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 differences:

- Cigarette Paper
  - Addition of (b) (4) and (b) (4)
  - Increase in (b) (4)
- Cigarette Paper bands
  - Addition of (b) (4) and (b) (4)
  - Increase in (b) (4)
- Tipping paper adhesive
  - Addition of (b) (4)

The added and increased ingredients in the new products were evaluated considering the potential to form HPHCs upon pyrolysis and inhalation exposures of these ingredients. In

addition, the HPHC smoke yields provided for SE0015539 (and considered applicable for the other SE Reports) were analytically equivalent between the new and predicate product for tar, nicotine, CO, acetaldehyde, acrolein, acrylonitrile, ammonia, benzene, benzo[a]pyrene, 1,3-butadiene, crotonaldehyde, formaldehyde, isoprene, toluene, 4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone (NNK) and N-nitrosonornicotine (NNN).

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

A finding of no significant impact (FONSI) was signed by Luis G. Valerio, Jr., Ph.D. on May 11, 2020. The FONSI was supported by an environmental assessment prepared by FDA on May 11, 2020.

6. CONCLUSION AND RECOMMENDATION

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

- Cigarette Paper Ingredients
  - Addition of (b) (4) mg/cig), (b) (4), and (b) (4)
  - Increase in (b) (4)
  - Removal of (b) (4) mg/cig)
- Cigarette Band Ingredients
  - Addition of (b) (4) mg/cig); addition of (b) (4) mg/cig)
  - Increase in (b) (4)
  - Removal of (b) (4) mg/cig)
- Monogram Ink Ingredients
  - Removal of (b) (4) mg/cig)
- Tipping Adhesive
  - Addition of (b) (4) mg/cig)
- Cigarette paper band porosity test data (CU): ↓41% (the target specifications and range limits are identical)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The applicant certified that the characteristics of the new and predicate tobacco products were identical in materials, ingredients, design features, heating source, or any other feature of the new product, except for the non-tobacco ingredients such as cigarette paper (including the cigarette band), monogram ink, and tipping adhesive. The characteristics between the current new products and corresponding predicate products are identical except for minor differences in the combusted portion of the cigarette. An issue regarding a decrease in the cigarette paper band porosity (i.e., band permeability) test data was identified, which was deferred to Chemistry from Engineering. The applicant submitted HPHC data for only new and predicate products in SE0015539. Because the tipping paper is not combusted, volatilized, or otherwise released during regular cigarette

consumption (and because the only differences between the new product in SE0015539 and the new tobacco products in SE0015540 and SE0015541 are in the tipping paper), a representative HPHC data set for SE0015539 is acceptable to extrapolate the HPHC smoke yields of the new and corresponding predicate tobacco products in SE0015540 and SE0015541. All TNCO and HPHC yields from ISO and CI smoking regimens were analytically equivalent via TOST analysis. 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 SE0015539, SE0015540, and SE0015541 were previously determined to be substantially equivalent by FDA under SE0014886, SE0014888, and SE0014890, 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 SE0015539, SE0015540, and SE0015541 were previously determined to be substantially equivalent by FDA under SE0014886, SE0014888, and SE0014890. Comparison of the new tobacco products in SE0015539, SE0015540, and SE0015541 to the grandfathered tobacco product (GF1200272; Marlboro 100's Soft Pack) reveals that the new tobacco products have the following differences in characteristics from the grandfathered tobacco product:

- Ingredient information on cigarette band
  - (b) (4) (↑ 594%)
  - (b) (4) (↑ 2.22 mg/cigarette)
  - (b) (4) (↑ 1.11 mg/cigarette)
- Ingredient information on cigarette paper
  - (b) (4) (↑ 100%)

The differences in characteristics identified for the new and grandfathered tobacco products in SE0014886, SE0014888, and SE0014890 are solely in the non-combusted portion of the cigarette. Therefore, these differences were not expected to affect the HPHC yields and did not cause the new products in SE0014886, SE0014888, and SE0014890 to raise different questions of public health. Therefore, these same differences between the new tobacco products in SE0015539, SE0015540, and SE0015541, in comparison to the GF product, do not cause the new tobacco products to raise different questions of public health. Additionally, as discussed above, because any differences between the new and predicate tobacco products in SE0015539, SE0015540, and SE0015541 resulted in analytically equivalent HPHCs yields the differences in between the new tobacco products in SE0015539, SE0015540, and SE0015541, the differences between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health. Therefore, whether comparing the new tobacco products in SE0015539, SE0015540, and SE0015541 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 SE0015539, SE0015540, and SE0015541, as identified on the cover page of this review.