FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0015576

SE0015576: 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
Common Attributes of SE Reports	
Applicant	Philip Morris USA Inc.
Report Type	Regular
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Recommendation	
Issue a Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Kenneth Taylor -S
Date: 2020.02.18 15:29:45 -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: 2020.02.19 08:38:42 -05'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0015576: 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 product is a combusted filtered cigarette manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On November 21, 2019, FDA received the SE Report (SE0015576), from Altria Client Services (ALCS) on behalf of Philip Morris USA Inc. On November 27, 2019, FDA issued an Acceptance letter for the SE Report.

Product Name	SE Report
Marlboro Black Special Blend Box	SE0015576

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific review completed for this SE Report.

2. REGULATORY REVIEW

A regulatory review was completed by Ester Hatton on November 27, 2019.

The review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco product in SE0015576 was determined to be substantially equivalent by FDA under SE0014279. Therefore, the predicate tobacco product is an eligible predicate tobacco product.

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the new tobacco product is 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 February 4, 2020, concludes that the new tobacco product is in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

A scientific review was completed by the Office of Science (OS) for the following disciplines:

4.1. CHEMISTRY

A chemistry review was completed by Selvin H. Edwards on January 13, 2020.

The chemistry review concludes that the new tobacco product has different characteristics related to product chemistry compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- Addition of (b) (4) (tipping adhesive)
- 14% increase in (b) (4) (cigarette paper)
- 104% increase in (b) (4) (cigarette paper)
- Addition of (b) (4) (cigarette paper)
- Addition of (b) (4) (Fire safe cigarette (FSC) bands)
- 593% increase in (b) (4) (FSC bands)
- 100% increase in (b) (4) (FSC bands)

Differences in cigarette paper ingredients, such as (b) (4), could alter the permeability of the cigarette paper, while difference in (b)(4) content can alter the burn rate of the cigarette, affecting the smoke yields of tar, nicotine, and carbon monoxide (TNCO), acetaldehyde, acrolein, crotonaldehyde and formaldehyde. Tipping adhesive is not combusted and therefore the ingredient change is not anticipated to affect smoke chemistry. The International Organization Standardization (ISO) non-intense and Canadian Intense smoking regimen yields of tar, nicotine, carbon monoxide, acetaldehyde, acrolein, acrylonitrile, ammonia, benzene, benzo-α-pyrene, 1,3-butadiene, crotonaldehyde, formaldehyde, isoprene, 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), N-Nitrosonornicotine (NNN), and toluene are analytically equivalent between the new and predicate products.

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

4.2. ENGINEERING

An engineering review was completed by Jimin P. Kim on January 9, 2020.

The engineering review did not identify any differences in characteristics between the new and predicate tobacco product that could cause the new tobacco product to raise different questions of public health from an engineering perspective.

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

4.3. TOXICOLOGY

A toxicology review was completed by Vyomesh Patel on January 9, 2020.

The toxicology review concludes that the new tobacco product has different characteristics related to product toxicology compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- Addition of (b) (4) to the cigarette paper
- Addition of (b) (4) to the cigarette paper bands
- Addition of (b) (4) to the tipping paper adhesive
- 104% increase in (b) (4) (cigarette paper)
- 593% increase in (b) (4) (FSC bands)

The added and increased ingredients in the new tobacco product were evaluated considering the potential to form HPHCs upon pyrolysis and inhalation exposures of these ingredients. As determined in the chemistry review, HPHCs are analytically equivalent between the new and predicate tobacco products. Also, as the tipping paper adhesive is not combusted, it is not anticipated to affect HPHC amounts and therefore is not a concern.

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

5. ENVIRONMENTAL DECISION

An environmental review was completed by Shannon K. Hanna on January 6, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on February 18, 2020. The FONSI was supported by an environmental assessment prepared by FDA on February 18, 2020.

6. CONCLUSION AND RECOMMENDATION

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

- Addition of [redacted] (tipping adhesive)
- 14% increase in [redacted] (cigarette paper)
- 104% increase in [redacted] (cigarette paper)
- Addition of [redacted] (cigarette paper)
- Addition of [redacted] (FSC bands)
- 593% increase in [redacted] (FSC bands)
  100% increase in [redacted] (FSC bands)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. The changes to the cigarette paper may affect smoke chemistry, whereas the change to the tipping adhesive should not since it is a non-combusted component. The ISO non-intense and Canadian Intense smoking regimen yields of tar, nicotine, carbon monoxide, acetaldehyde, acrolein, acrylonitrile, ammonia, benzene, benzo-α-pyrene, 1,3-butadiene, crotonaldehyde, formaldehyde, isoprene, NNK, NNN, and toluene are analytically equivalent between the new and predicate products. Therefore, the differences in characteristics between the new and predicate products do not cause the new tobacco product to raise different questions of public health.

The predicate tobacco product was previously determined to be substantially equivalent by FDA under 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 product in SE0015576 was previously determined to be substantially equivalent by FDA under SE0014279. Comparison of the new tobacco product to the grandfathered product Marlboro Soft Pack in SE0014279 reveals that the new tobacco product has the following differences in characteristics from Marlboro Soft Pack, the grandfathered tobacco product:

- Increases in [redacted] (250%), [redacted] (290%), [redacted] (112%), and [redacted] (100%) (tipping adhesive)
- Addition of [redacted] (added), [redacted] (tipping adhesive)
- 800% increase in [redacted] (monogram ink)
- Respective increases of 14% and 104% in [redacted] (cigarette paper)
- Addition of [redacted] (cigarette paper)

The differences in characteristics listed above, other than the differences in monogram ink and some other ingredient differences in the tipping adhesive and cigarette paper, are the same differences in characteristics identified for the new and grandfathered tobacco product in SE0014279. Therefore, these differences do not cause the new tobacco product in SE0015576 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in monogram ink and some ingredient differences in the tipping adhesive and cigarette paper between the new

tobacco product in SE0015576 and the grandfathered tobacco product do not cause the new tobacco product to raise different questions of public health. Therefore, whether comparing the new tobacco product in in SE0015576 to the predicate of grandfathered tobacco product, the new tobacco product does not raise different questions of public health.

The new tobacco product is 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 product does 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 this new tobacco product substantially equivalent and made a finding of no significant impact.

An SE order letter should be issued for the new tobacco product in SE0015576, as identified on the cover page of this review.