FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review:

SE0007204

SE0007204: Marlboro Southern Cut 100's Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98.5 mm
Diameter	7.89 mm
Ventilation	18%
Characterizing Flavor	None
Additional Property	Cigarette Paper-1[1]
Common Attributes of SE Report	
Applicant	Philip Morris USA, Inc.
Report Type	Regular
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Recommendation	
Issue a Substantially Equivalent (SE) order.	

[1] In the original SE Report dated December 7, 2012, the applicant included information about 3 different cigarette papers: Cigarette Paper-1, Cigarette Paper-2, and Cigarette Paper-3. In the amendment SE0013575, dated August 11, 2016, the applicant removed Cigarette Paper-2, and Cigarette Paper-3 from review.

Technical Project Lead (TPL):

Matthew J. Walters -S
2017.12.22 10:02:25 -05'00'

Matthew Walters, Ph.D., MPH
CDR, US Public Health Service
Deputy Director
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: 2017.12.22 10:40:05 -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:

SE0007204: Marlboro Southern Cut 100's Box	
Product Name	Marlboro 100's Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98 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

FDA received the SE Report for the tobacco product listed above from Altria Client Services, LLC on behalf of Philip Morris USA, Inc. on February 14, 2013. FDA acknowledged the SE Report on March 15, 2013. FDA issued an Advice/Information Request (A/I) letter on March 15, 2013. In response to the A/I letter, the applicant submitted an amendment (SE0008798) on May 30, 2013. On December 6, 2013, FDA issued a Notification letter indicating that scientific review of the SE Report would begin on January 20, 2014 and FDA would review all amendments received no later than January 19, 2014. The applicant submitted an amendment (SE0010111) on January 16, 2014, to provide additional information for the SE Report. The applicant submitted amendment (SE0012368) on September 18, 2015, to provide corrections to the SE Report and the amendment (SE0010111). FDA issued an A/I letter on June 14, 2016. In response to the A/I letter, the applicant submitted an amendment (SE0013575) on August 11, 2016. The applicant submitted amendment (SE0013673) on August 30, 2016, to correct an error noted in the September 18, 2015 amendment (SE0012368). FDA issued a Preliminary Finding (PFind) letter on May 3, 2017. In response to the PFind letter, the applicant submitted an amendment (SE0014128) on June 1, 2017. FDA issued a PFind letter identifying environmental assessment deficiencies for the SE Report on August 29, 2017. In response to the PFind letter, the applicant submitted an amendment (SE0014349) on September 26, 2017.

Product Name	SE Report	Amendments
Marlboro Southern Cut 100's Box	SE0007204	SE0008798 SE0010111 SE0012368 SE0013575 SE0013673 SE0014128 SE0014349

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

Regulatory completeness reviews were completed by Nathan Hurley on March 15, 2013, and February 26, 2014.

The final review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed review to determine whether the applicant established that the predicate tobacco product is a grandfathered product (i.e., was commercially marketed as of February 15, 2007). The OCE review dated December 19, 2013, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and, therefore, is an eligible predicate tobacco product.

OCE also 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 November 21, 2017, concludes that the new tobacco product is 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 An Vu on March 19, 2014, Jui Ai on October 26, 2016, and Andre Williams on July 12, 2017.

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

- The new product contains lower quantities of (b) (4) compared to the predicate product.
- The new product contains higher amounts ((b) (4) increase) of (b) (4) compared to the predicate product.
- Ingredient amounts in the new product decrease in the cigarette paper and tobacco blend, but increase in the filter system to accommodate the longer filter of the new product.

- The new and predicate products have different cigarette seam adhesives that contain different ingredients.
- The new and predicate products have different base tipping papers that contain different ingredients. The new product has more tipping material than the predicate product because the new product has a longer filter.
- The new product contains flavoring ingredients that were not present in the predicate product.
- The new product contains (b) (4) that was not present in the predicate product.

The new product showed a decrease of approximately (b) (4) of the total tobacco blend compared to the predicate product and this decrease in the tobacco blend does not result in increased harmful and potentially harmful constituent (HPHC) yields as evidenced by a reduction in a number of HPHCs including benzo[a]pyrene, carbon monoxide, nicotine, and NNK. Additionally, the new and predicate products contain different amounts and types of tobacco. The new product contains (b) (4) more of (b) (4) which is about (b) (4) change of the total tobacco filler mass. Because this change is considered minimal, the difference in (b) (4) between the new and predicate tobacco products does not cause the new product to raise different questions of public health. Further, there are differences in the ingredients of both the tipping papers and cigarette seam adhesives in the new product as compared to the predicate product; however, these ingredients contribute less than (b) (4) of the overall product mass and since these ingredient differences are minimal, these differences do not significantly impact HPHC smoke yields in the new product as indicated by a reduction in a number of HPHCs including benzo[a]pyrene, carbon monoxide, nicotine, and NNK. Although not addressed by the chemistry review,[2] the new product contains flavoring ingredients that were not present in the predicate product; however, these ingredients are present at very low levels (below (b) (4) mg/cigarette) and therefore do not cause the new product to raise different questions of public health. The new product contains (b) (4) that was not present in the predicate product. The addition of (b) (4) to tobacco can increase the quantity of nicotine by less than (b) (4) mg/cigarette but this addition does not have a significant impact on the nicotine delivery of the new product as evidenced by the reduction in nicotine smoke yields; thus this change does not cause the new product to raise different questions of public health. 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 James Melchiors on March 27, 2014, and Michael Morschauser on October 26, 2016, and July 12, 2017.

The final engineering review concludes that the new tobacco product has different characteristics related to product design compared to the predicate tobacco product but the differences do not cause the new tobacco product to raise different questions of public health

[2] The chemistry review deferred evaluation of flavoring ingredients to social science to determine whether the addition of flavoring ingredients in the new product caused the product to raise different questions of public health. I note the chemistry review should not have deferred this review to social science.

from an engineering perspective. The review identified the following differences related to product design:

- Decrease in base paper porosity.
- Increases in filter and tipping paper length, pressure drop, and ventilation.
- Increase in product length and decrease in tobacco rod length.

The new tobacco product cigarette paper base paper porosity is substantially lower than the predicate product. Analysis of smoke yields showed a decrease in TNCO, NNK, and B[a]P; therefore, the decrease in porosity was deemed acceptable given the decrease in HPHC yields and does not cause the new product to raise different questions of public health. The new product has an increase in filter length compared to the predicate product, as well as an increase in ventilation. These were both deemed acceptable changes, as evidenced by the reduction in HPHC smoke yields provided by the applicant and therefore do not cause the new product to raise different questions of public health. The increase in filter length also necessitates an increase in tipping paper length, and results in a corresponding increase in filter pressure drop, however given the reduction in a number of HPHCS, these changes do not cause the new product to raise different questions of public health. The new product is longer than the predicate product, and it has a shorter tobacco rod. Such differences can impact the mass of the tobacco product, and in this case the tobacco mass difference is (b) (4) (b) (4) for the new product. Less tobacco filler mass may decrease smoke yield constituents. Evaluation of the reported smoke constituent deliveries showed a decrease in TNCO, NNK, and B[a]P, thus the changes in product length and tobacco rod length do not cause the new product to raise different questions of public health. 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 related to product design from an engineering perspective.

4.3. TOXICOLOGY

Toxicology reviews were completed by Mary Kushman on May 5, 2016, and Lynn Crosby on April 24, 2017, and July 27, 2017.

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

- The new and predicate products have different cigarette seam adhesives that contain different ingredients.
- The new and predicate products have different base tipping papers that contain different ingredients. The new product has more tipping material than the predicate product because the new product has a longer filter.
- The new product contains flavoring ingredients that were not present in the predicate product.

- Reduction in HPHC yields

There are differences in the ingredients of both the tipping papers and cigarette seam adhesives in the new product as compared to the predicate product; however, these ingredients contribute less than (b) (4) of the overall product mass and since these ingredient differences are minimal they do not significantly impact HPHC smoke yields in the new product, as indicated by a reduction in a number of HPHCs including benzo[a]pyrene, carbon monoxide, nicotine, and NNK. Additionally, the new product contains flavoring ingredients that were not present in the predicate product; however, these ingredients are present at very low levels (below (b) (4) mg/cigarette) and therefore do not cause the new product to raise different questions of public health. 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 toxicology perspective.

4.4. SOCIAL SCIENCE

Social science review was completed by Amber Koblitz on April 7, 2014.

The final social science review concludes that the characteristics are different for the new and predicate tobacco products, but the differences do not cause the new tobacco product to raise different questions of public health from a social science perspective. The review identified the following difference related to:

- Changes in the flavor ingredients

The new tobacco product contained some flavor ingredient difference compared to the predicate product. Social science review deferred all ingredient changes made in the new product compared to the predicate product to chemistry to determine whether the difference causes the new tobacco product to raise different questions of public health. While the final chemistry reviewer did not make a determination on the difference in flavor ingredients, I concluded above that because the new flavor ingredients are present at very low levels, this difference does not cause the new product to raise different questions of public health from a chemistry perspective. Additionally, despite the difference in flavor ingredients between the new and predicate products, both the new and predicate products have no characterizing flavor. Because social science generally reviews flavor changes as it relates to consumer perception of the tobacco product, and there is no change in characterizing flavor of the product, I again conclude that the difference in flavor ingredients does not cause the new product to raise different questions of public health. Therefore, the difference in characteristics between the new and predicate tobacco product does not cause the new tobacco product to raise different questions of public health from a social science perspective.

The review also evaluated the health information summary and determined that it did not violate section 911(b)(2)(A)(i)(II) of the FD&C Act. Therefore, the final review did not identify a deficiency related to the health information summary.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on December 22, 2017. The FONSI was supported by an environmental assessment prepared by FDA on December 22, 2017.

6. CONCLUSION AND RECOMMENDATION

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

- The new product contains lower quantities of (b) (4) compared to the predicate product.
- Ingredient amounts in the new product decrease in the cigarette paper and tobacco blend, but increase in the filter system to accommodate the longer filter of the new product.
- The new and predicate products have different cigarette seam adhesives that contain different ingredients.
- The new and predicate products have different base tipping papers that contain different ingredients. The new product has more tipping material than the predicate product because the new product has a longer filter.
- The new product contains flavoring ingredients that were not present in the predicate product.
- The new product contains (b) (4) that was not present in the predicate product.
- The new product contains higher amounts ((b) (4)) of (b) (4) compared to the predicate product.
- Increases in filter and tipping paper length, pressure drop, and ventilation.
- Decrease in base paper porosity.
- Increase in product length and decrease in tobacco rod length.
- Reduction in HPHC yields.

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. The tobacco blend of the new product decreased compared to the predicate product. In addition, many ingredients such as the ingredients in the cigarette seam adhesives and base tipping paper in the new product decreased in quantity compared to the predicate tobacco product. The new product contains flavoring ingredients that were not present in the predicate product; however, these ingredients are present at very low levels (below (b) (4) /cigarette) and therefore do not cause the new product to raise different questions of public health. Furthermore, there was a reduction in HPHC yields including benzo[a]pyrene, carbon monoxide, nicotine, and NNK even as some of the engineering design parameters (i.e. filter, tipping paper length, ventilation, and pressure drop) changed. As a result, these changes do not cause the new product to raise different questions of public health. 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 meets statutory requirements because it is a grandfathered product (i.e., was commercially marketed in the United States as of February 15, 2007).

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 predicate tobacco products are such that the differences do not cause the new tobacco product to 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 this new tobacco product substantially equivalent and made a finding of no significant impact.

A SE order letter should be issued for the new tobacco product in SE0007204, as identified on the cover page of this review.