

Technical Project Lead (TPL) Review:

SE0014279, SE0014280, and SE0014281

| SE0014279: Marlboro Soft Pack | |
|---|------------------------|
| Package Type | Soft Pack |
| Package Quantity | 20 cigarettes |
| Length | 84 mm |
| Diameter | 7.89 mm |
| Ventilation | 15% |
| Characterizing Flavor | None |
| SE0014280: Marlboro Menthol Box | |
| Package Type | Hard Pack |
| Package Quantity | 20 cigarettes |
| Length | 83 mm |
| Diameter | 7.89 mm |
| Ventilation | 21% |
| Characterizing Flavor | Menthol |
| SE0014281: Marlboro Box | |
| Package Type | Hard Pack |
| Package Quantity | 20 cigarettes |
| Length | 79 mm |
| Diameter | 7.89 mm |
| Ventilation | 12% |
| 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: 2018.04.19 14:43:25 -04'00'

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: 2018.04.19 14:49:18 -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:

| SE0014279: Marlboro Soft Pack | |
|--|----------------------|
| 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 |
| SE0014280: Marlboro Menthol Box | |
| Product Name | Marlboro Menthol Box |
| Package Type | Hard Pack |
| Package Quantity | 20 cigarettes |
| Length | 83 mm |
| Diameter | 7.89 mm |
| Ventilation | 21% |
| Characterizing Flavor | Menthol |
| SE0014281: Marlboro Box | |
| Product Name | Marlboro Box |
| Package Type | Hard Pack |
| Package Quantity | 20 cigarettes |
| Length | 79 mm |
| Diameter | 7.89 mm |
| Ventilation | 12% |
| Characterizing Flavor | None |

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received three SE Reports (SE0014279, SE0014280, and SE0014281) on August 28, 2017, which were submitted by Altria Client Services Inc. (ALCS) on behalf of Philip Morris USA Inc. (PM USA). FDA acknowledged the SE Reports on September 1, 2017. FDA issued an Advice/Information Request (A/I) letter on November 22, 2017. On January 19, 2018, FDA received the response to the A/I letter (SE0014474).

| Product Name | SE Report | Amendments |
|----------------------|-----------|------------|
| Marlboro Soft Pack | SE0014279 | SE0014474 |
| Marlboro Menthol Box | SE0014280 | |
| Marlboro Box | SE0014281 | |

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 Pin Zhang on September 1, 2017.

The reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate tobacco products are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated October 5, 2017, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered and, therefore, are eligible predicate tobacco products¹.

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 dated April 13, 2018 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 Jiu Ai on October 23, 2017, and March 7, 2018.

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:

¹ Addendum reviews were completed on April 6, 2018, to clarify the package type and size for the predicate and new tobacco products. Since the initial grandfather determination on October 5, 2017, was based on a product of that package type and size, the addendum reviews do not change the conclusion of the initial determination.

- Ingredient differences in tipping ink and tipping ink extender
- Removal of (b) (4) [SE0014280 only]

The tipping ink and tipping ink extender are not combusted and therefore, the ingredient differences do not cause the new tobacco products to raise different questions of public health. Likewise, the removal of a small amount of the (b) (4) (b) (4) /cigarette) in the tobacco filler of the new tobacco product of SE0014280 is a less than 1 millionth change relative to the weight of the tobacco filler alone. This ingredient change is not significant in consideration of the total weight of the entire cigarette.

Therefore, the chemistry review concludes 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 chemistry perspective.

4.2. ENGINEERING

Engineering reviews were completed by Rashele Moore on October 20, 2017, and March 7, 2018.

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 puff count as the only design parameter that differed between the new and corresponding predicate tobacco products. In the new tobacco products, puff count:

- Increases for SE0014279 by 2%
- Decreases in SE0014280 by 3%
- Increases in SE0014281 by 6%²

The applicant provided the target specifications and range limits for the requested design parameters, for all new and corresponding predicate tobacco products for all SE Reports. The applicant was also asked to provide test data for design parameters. The applicant adequately provided test data for the new and predicate tobacco products for all design parameters for all SE Reports. The only difference observed with the provided test data was an increase in puff count for SE0014279 and SE0014281 and a decrease in puff count for SE0014280. Puff count is influenced by many design parameters, including cigarette paper and tobacco blend. As noted in the chemistry review, there is no change in the tobacco blend, cigarette paper, or the cigarette design features. Since there are no differences in these characteristics which would affect puff count, the observed changes in puff count are considered to be analytical artefacts.

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.

² Data provided shows an increase in puff count, but the engineering review incorrectly indicates a decrease.

4.3. TOXICOLOGY

A toxicology review was completed by Jueichuan Kang on October 29, 2017.

The toxicology review concludes that the new tobacco product in SE0014280 has different characteristics related to toxicology compared to the predicate tobacco product but the difference does not cause the new tobacco product to raise different questions of public health. The review identified the following difference:

- Removal of (b) (4)

The review concludes that the removal of (b) (4) as a non-tobacco ingredient will not change the chemistry profile of the new tobacco product. As explained in the Chemistry review section, this change is negligible due to the extremely small amount of (b) (4)

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

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 19, 2018. The FONSI was supported by an environmental assessment prepared by FDA on April 19, 2018.

6. CONCLUSION AND RECOMMENDATION

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

- Ingredient differences in tipping ink and tipping ink extender
- Removal of (b) (4) [SE0014280 only]

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The tipping ink and tipping ink extender are not combusted and, therefore, the ingredient differences do not cause the new tobacco products to raise different questions of public health. Likewise, the removal of a small amount of the (b) (4) (b) (4) /cigarette) in the tobacco filler of the new product of SE0014280 is not a concern. 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 meet statutory requirements because it was determined that they are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

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 the corresponding predicate

tobacco products do not cause the new tobacco products to raise different questions of public health. I concur with the discipline reviews and I 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 SE0014279, SE0014280, and SE0014281, as identified on the cover page of this review.