

Technical Project Lead (TPL) Review: SE0015605 and SE0015606

SE0015605: Marlboro Edge Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 millimeters (mm)
Diameter	7.89 mm
Ventilation	17%
Characterizing Flavor	None
SE0015606: Marlboro Menthol Smooth Ice Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	34%
Characterizing Flavor	Menthol
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 Charles Feng -S
Date: 2020.03.03 14:52:07 -05'00'

Charles Feng, 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: 2020.03.03 15:23:50 -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:

SE0015605: Marlboro Edge Box	
Product Name	Marlboro Edge Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	17%
Characterizing Flavor	None
SE0015606: Marlboro Menthol Smooth Ice Box	
Product Name	Marlboro Menthol Gold Pack Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	34%
Characterizing Flavor	Menthol

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On December 10, 2019, FDA received SE Reports (SE0015605 and SE0015606) from Altria Client Services LLC (ALCS) on behalf of Philip Morris USA Inc. (PM USA). On December 17, 2019, FDA issued an Acceptance letter to the applicant.

Product Name	SE Report	Amendments
Marlboro Edge Box	SE0015605	None
Marlboro Menthol Smooth Ice Box	SE0015606	None

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 December 17, 2019.

The reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco products in SE0015605 and SE0015606 were determined to be substantially equivalent by FDA under SE0014887 and SE0014203, 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 section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated February 10, 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 review was completed by DeLauren McCauley on January 22, 2020.

The chemistry review concludes that the new tobacco products have different characteristics related to product chemistry compared to the 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:

- Increases (e.g., (b) (4) [redacted]) and decreases (e.g., (b) (4) [redacted]) in cigarette paper ingredients resulting in a total of 0.6% increase for SE0015605 and 5% for SE0015606 in cigarette paper ingredients
- 9% total decrease in monogram ink ingredients (SE0015605)
- Increases (e.g., (b) (4) [redacted]) and decreases (e.g., (b) (4) [redacted]) in plug wrap ingredients resulting in a total of 9% decrease in plug wrap ingredients (SE0015606)
- Addition of (b) (4) [redacted] mg/cigarette) in tipping adhesive

The decrease in monogram ink in SE0015605 does not raise concerns because this change reduces the harmful and potential harmful constituents (HPHC) formation. Tipping adhesive and plug wraps are not combusted during normal use, and therefore, the reported ingredient changes in these components do not raise any concerns from a chemistry perspective. However, the changes in cigarette paper (including band) ingredients may cause the new tobacco products to raise different questions of public health because such changes may impact the smoke yields of HPHCs such as carbonyls and benzene). However, the submitted tar and HPHC smoke yields including nicotine, carbon monoxide, acetaldehyde, acrolein, acrylonitrile, ammonia, benzene, benzo[a]pyrene, crotonaldehyde, formaldehyde, isoprene, NNK, NNN, and toluene, are analytically equivalent between the new and corresponding

predicate tobacco products under both ISO and CI smoking regimens. Therefore, the cigarette paper ingredient differences do not cause the new tobacco products 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 products to raise different questions of public health from a chemistry perspective.

4.2. ENGINEERING

Engineering review was completed by Drew Katherine on January 20, 2020.

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:

- 1% decrease in cigarette paper band space
- 5% increase in cigarette paper band width

Both new tobacco products have a 1% decrease in cigarette paper band space compared to the corresponding predicate tobacco products. This difference is anticipated to be too small to affect the smoke chemistry. Both new tobacco products also have a 5% increase in cigarette paper band width, compared to their corresponding predicate tobacco products, which may increase TNCO smoke yields. The yields of TNCO are deferred to chemistry for evaluation. 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

Toxicology review was completed by Luis M. DaSilva on January 28, 2020.

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:

- Additions or increases in cigarette paper ingredients including (b) (4) materials, (b) (4)
- Addition of (b) (4) mg/cigarette) in the tipping adhesive
- Addition of (b) (4) in the plug wrap (SE0015606)

The ingredient changes in cigarette paper have the potential to change smoke yields of some HPHCs (e.g., CO, carbonyls, and benzene); however, the HPHC data indicate no analytically non-equivalent increases in the new tobacco products when compared to the corresponding predicate tobacco products. As a volatile compound, (b) (4) was added to the

tipping adhesive, which is not combusted during normal smoking. Any residual (b) (4) is not expected to be burned, or be a potential source of HPHC generation, or otherwise released during normal cigarette consumption conditions. For SE0015606, (b) (4) were added to the plug wrap. Plug wrap is a non-combusted portion of the cigarette; these ingredients are not expected to undergo combustion, pyrolysis to generate additional HPHCs, or enter mainstream smoke under normal cigarette consumption conditions.

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 Kimberly Benson, Ph.D. on January 28, 2020. The FONSI was supported by an environmental assessment prepared by FDA on January 28, 2020.

6. CONCLUSION AND RECOMMENDATION

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

- 5% increase in cigarette paper band width
- Addition or increases in cigarette paper ingredients including (b) (4) materials, (b) (4)
- Addition of (b) (4) mg/cigarette) in the tipping adhesive
- Increases (e.g., (b) (4)) and decreases (e.g., (b) (4)) in plug wrap ingredients resulting in a total of 9% decrease in plug wrap ingredients (SE0015606)
- 9% total decrease in monogram ink (SE0015605)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. Changes in tipping adhesive and plug wrap are mostly small. Additionally, these components are not combusted during normal smoking. Therefore, changes in these ingredients are not expected to affect smoke chemistry. Thus, exposure to these ingredients via the oral, inhalation, or dermal route of exposure is expected to be negligible, from a toxicology perspective. A decrease in monogram ink ingredients on the cigarette barrel (SE0015605) reduces the formation of HPHCs, and therefore, does not raise any concerns. However, an increase in (b) (4) a flame retardant, may increase smoke yields, whereas increases in (b) (4), burn accelerators, may decrease smoke yields. Moreover, additions or increases in cigarette paper ingredients including (b) (4) materials, (b) (4) have the potential to increase HPHC yields such as carbonyls (e.g., acetaldehyde, acrolein, and formaldehyde) and volatile organic compounds (e.g., benzene). In terms of the design parameters, a 5% increase in cigarette paper band width may increase TNCO yields. To address the combined effects of all these changes, the applicant provided mainstream smoke yields for TNCO and other HPHCs including acetaldehyde, acrolein, acrylonitrile, ammonia, benzene, benzo[a]pyrene, crotonaldehyde, formaldehyde, isoprene, NNK, NNN, and toluene obtained using both the ISO and

CI smoking regimens. A statistical comparison of the submitted data indicates that all HPHC yields in the new tobacco products are analytically equivalent to the respective yields in the corresponding predicate tobacco products. 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.

The predicate tobacco products were previously determined to be substantially equivalent by FDA under SE0014887 and SE0014203.

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 SE0015605 and SE0015606 were previously determined to be substantially equivalent by FDA under SE0014887 and SE0014203, respectively. Comparison of the new tobacco products to the grandfathered tobacco products (Chesterfield Box in SE0014887 and Marlboro Lights Menthol Box in SE0014203) reveals that the new tobacco products have the following differences in characteristics from the Chesterfield Box and the Marlboro Lights Menthol Box, the grandfathered tobacco products:

- Tipping paper and ink composition differences, including additions and increases (SE0015605)
- Removal of (b)(4) (SE0015606)
- 5% increase in cigarette paper band width
- Addition or increases in cigarette paper ingredients including (b)(4) materials, (b)(4)
- Addition of (b)(4) mg/cigarette) in the tipping adhesive
- Increases (e.g., (b)(4) and decreases (e.g., (b)(4) in plug wrap ingredients resulting in a total of 9% decrease in plug wrap ingredients (SE0015606)
- 9% total decrease in monogram ink (SE0015605)

The differences in characteristics listed above, other than the differences in cigarette paper (band width and ingredients), tipping adhesive, plug wrap, and monogram ink on cigarette barrel, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0014887 and SE0014203. Therefore, these differences do not cause the new tobacco products in SE0015605 and SE0015606 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in cigarette paper (band width and ingredients), tipping adhesive, plug wrap, and monogram ink between the new tobacco products in SE0015605 and SE0015606 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 SE0015605 and SE0015606, 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 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 SE0015605 and SE0015606, as identified on the cover page of this review.