

Technical Project Lead (TPL) Review: SE0015726 – SE0015730

SE0015726: Chesterfield 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.0 millimeters (mm)
Diameter¹	7.89 mm
Ventilation	None
Characterizing Flavor	None
SE0015727: Chesterfield Menthol 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	99.0 mm
Diameter¹	7.89 mm
Ventilation	None
Characterizing Flavor	Menthol
SE0015728: Benson & Hedges 100's Deluxe Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter¹	7.64 mm
Ventilation	55%
Characterizing Flavor	None
SE0015729: Merit Blue Pack 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter¹	7.89 mm
Ventilation	55%
Characterizing Flavor	None
SE0015730: L&M Turkish Blend 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter¹	7.64 mm
Ventilation	17%
Characterizing Flavor	None

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

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 Jeannie H. Jeong-im -S
Date: 2020.08.31 12:03:16 -04'00'

Jeannie Jeong-Im, 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: 2020.08.31 12:13:15 -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:

SE0015726: Chesterfield 100's Box	
Product Name	Chesterfield 100's Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.0 mm
Diameter¹	7.89 mm
Ventilation	None
Characterizing Flavor	None
SE0015727: Chesterfield Menthol 100's Box	
Product Name	Chesterfield Menthol 100's Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	99.0 mm
Diameter¹	7.89 mm
Ventilation	None
Characterizing Flavor	Menthol
SE0015728: Benson & Hedges 100's Deluxe Box	
Product Name	Benson & Hedges 100's Deluxe Ultra Lights Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter¹	7.64 mm
Ventilation	55%
Characterizing Flavor	None
SE0015729: Merit Blue Pack 100's Box	
Product Name	Merit Blue Pack 100's Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter¹	7.89 mm
Ventilation	55%
Characterizing Flavor	None

SE0015730: L&M Turkish Blend 100's Box	
Product Name	L&M Turkish Blend 100's Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter¹	7.64 mm
Ventilation	17%
Characterizing Flavor	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On February 26, 2020, FDA received five SE Reports from Altria Client Services LLC, on behalf of Philip Morris USA Inc. On March 5, 2020, FDA issued an Acceptance letter. On April 24, 2020, FDA issued a Deficiency letter to the applicant. On June 3, 2020, FDA received an amendment (SE0016638) containing a response to the Deficiency letter.

Product Name	SE Report	Amendment
Chesterfield 100's Box	SE0015726	SE0016638
Chesterfield Menthol 100's Box	SE0015727	
Benson & Hedges 100's Deluxe Box	SE0015728	
Merit Blue Pack 100's Box	SE0015729	
L&M Turkish Blend 100's Box	SE0015730	

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 March 4, 2020.

The reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the predicate tobacco product in SE0015728 is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE review March 26, 2020, concludes that the evidence submitted by the

applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and therefore an eligible predicate tobacco product.

The predicate tobacco products in SE0015726, SE0015727, SE0015729, and SE0015730 were determined to be substantially equivalent by FDA under SE0014817, SE0014818, SE0014912, and SE0014915, respectively. Therefore, these products are eligible predicate tobacco products.

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 July 30, 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 Yuan-wei Nei on April 16, 2020 and July 13, 2020.

The final 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:

- All SE Reports
 - Cigarette seam adhesive
 - 47–48% less (b) (4) mg/cigarette)
 - 367–377% higher (b) (4) mg/cigarette)
 - Deletion of (b) (4) mg/cigarette)
 - Addition of (b) (4) mg/cigarette)
 - Addition of (b) (4) mg/cigarette)
 - Addition of (b) (4) mg/cigarette)
 - Tipping adhesive
 - Addition of (b) (4) mg/cigarette)
- SE0015726: Monogram Ink
 - 13% less (b) (4) µg/cigarette)
 - 7% less (b) (4) µg/cigarette)
 - 10% less (b) (4) µg/cigarette)
 - 9% less (b) (4) µg/cigarette)
 - 7% less (b) (4) µg/cigarette)
 - 17% less (b) (4) µg/cigarette)
 - 9% less (b) (4) µg/cigarette)
 - 11% less (b) (4) µg/cigarette)
 - 9% less (b) (4) µg/cigarette)

- Deletion of (b) (4) µg/cigarette)

For all corresponding SE Reports, the ingredients and design features were the same except for the cigarette seam adhesive, monogram ink, and tipping adhesive as listed above. The applicant provided a summary of the results for all Harmful and Potential Harmful Constituent (HPHC) testing performed under ISO and Canadian Intense (CI) smoking regimens. The HPHC list includes carbonyls, volatile organic compounds, B[a]P, ammonia, NNN, NNK, and TNCO. Differences in HPHC yields in mainstream smoke (MSS) between the new and corresponding predicate tobacco products were analyzed and determined to be analytical equivalent by TOST² under both ISO and CI regimens. 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. TOXICOLOGY

A toxicology review was completed by Luis Dasilva on April 15, 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:

All SE Reports

- Cigarette seam adhesive
 - (b) (4) (added; (b) (4) mg/cig)
 - (b) (4) (added; (b) (4) mg/cig)
 - (b) (4) (added; (b) (4) mg/cig)
- Tipping adhesive: (b) (4) (added; (b) (4) mg/cig)
- HPHCs: all HPHCs are analytically equivalent.

SE0015726

- Monogram ink: decreased levels of multiple ingredients

For all SE Reports, there are changes in the cigarette seam adhesive and tipping adhesive of the new tobacco products, compared to the corresponding predicate tobacco products. These changes include addition of (b) (4) to the cigarette seam adhesive, and (b) (4) to the tipping adhesive. The added cigarette seam adhesive ingredients can pyrolyze to form the following HPHCs in MSS:

- (b) (4) : benzene
- (b) (4) : acetaldehyde, acrolein, formaldehyde

For all five SE Reports, the applicant provided data for the aforementioned HPHCs in MSS smoke under ISO and CI regimens, and these HPHC levels are analytically equivalent between

² Two One-Sided T-test (TOST) is a statistical tool that calculates important analytical differences (IADs) using the Horwitz-Thompson equation.

the new and corresponding predicate tobacco products by a TOST analysis. Levels of the (b) (4) expected to be retained in the new products in all SE Reports are unlikely to raise concerns from a toxicological perspective. The new product of SE0015726 also has decreased levels of multiple monogram ink ingredients. 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

Environmental reviews were completed by Ronald Edwards on April 6, 2020 and July 1, 2020.

A finding of no significant impact (FONSI) was signed by Luis G. Valerio Jr., Ph.D., ATS on July 6, 2020. The FONSI was supported by an environmental assessment prepared by FDA on July 6, 2020.

6. CONCLUSION AND RECOMMENDATION

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

- All SE Reports
 - Cigarette seam adhesive
 - 47–48% less (b) (4) mg/cigarette)
 - 367–377% higher (b) (4) mg/cigarette)
 - Deletion of (b) (4) mg/cigarette)
 - Addition of (b) (4) mg/cigarette)
 - Addition of (b) (4) mg/cigarette)
 - Addition of (b) (4) ingredient (b) (4) mg/cigarette) in the cigarette seam adhesive for all SE Reports
 - Tipping adhesive
 - Addition of (b) (4) mg/cigarette)
- SE0015726: Monogram Ink
 - 13% less (b) (4) µg/cigarette)
 - 7% less (b) (4) µg/cigarette)
 - 10% less (b) (4) µg/cigarette)
 - 9% less (b) (4) µg/cigarette)
 - 7% less (b) (4) µg/cigarette)
 - 17% less (b) (4) µg/cigarette)
 - 9% less (b) (4) µg/cigarette)
 - 11% less (b) (4) µg/cigarette)
 - 9% less (b) (4) µg/cigarette)
 - Deletion of (b) (4) µg/cigarette)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. There are changes in ingredients to the cigarette seam adhesive and tipping adhesive. Also, there are changes to the monogram ink in SE0015726. The applicant provided TNCO, acetaldehyde, acrolein, acrylonitrile, ammonia, benzene, benzo[a]pyrene, 1,3-butadiene, crotonaldehyde, formaldehyde, isoprene, NNK, NNN, and toluene yields under ISO and CI smoking regimens. All the HPHCs were equivalent under TOST. 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 product in SE0015728 meet statutory requirements because it was determined that it was a grandfathered tobacco product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The predicate tobacco products in SE0015726, SE0015727, SE0015729, and SE0015730 were previously determined to be substantially equivalent by FDA under SE0014818, SE0014817, SE0014912, and SE0014915, respectively.

Where an applicant supports a showing of substantial equivalence 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 SE0015726, SE0015727, SE0015729, and SE0015730 were previously determined to be substantially equivalent by FDA under SE0014818, SE0014817, SE0014912, and SE0014915, respectively. Comparison of the new tobacco products to the grandfathered tobacco products (Basic Full Flavor 100's Box in SE0014818, Basic Menthol 100's Soft Pack in SE0014817, Merit Ultra Lights 100's Box in SE0014912 and Players 100's Box in SE0014915) reveals that the new tobacco products have the following differences in characteristics from Basic Full Flavor 100's Box, Basic Menthol 100's Soft Pack, Ultra Lights 100's Box, and Players 100's Box, the grandfathered tobacco products:

- Base tipping paper
- Tipping ink extender
- Tipping adhesive
- Cigarette seam adhesive
- Inks (except for SE0015726)

The differences in characteristics listed above, other than the differences in base tipping paper, tipping ink extender, and inks, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0014818, SE0014817, SE0014912, and SE0014915. Therefore, these differences do not cause the new tobacco products in SE0015726, SE0015727, SE0015729, and SE0015730 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in cigarette seam adhesive, tipping adhesive, and inks (SE0015726 only) between the new tobacco products in SE0015726, SE0015727, SE0015729, and SE0015730 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 SE0015726, SE0015727, SE0015729, and SE0015730 to 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 SE0015726 – SE0015730, as identified on the cover page of this review.