

Technical Project Lead (TPL) Review: SE0015736–SE0015738 and SE0015741–SE0015743

SE0015736: Benson & Hedges 100's Luxury Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	99.5 mm
Diameter ¹	7.89 mm
Ventilation	30%
Characterizing Flavor	None
SE0015737: L&M Menthol Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	84.0 mm
Diameter ¹	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 1
SE0015738: Marlboro Menthol Special Select 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter ¹	7.89 mm
Ventilation	15%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 1
SE0015741: L&M Menthol Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	84.0 mm
Diameter ¹	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 2

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

SE0015742: L&M Menthol Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	84.0 mm
Diameter¹	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 3
SE0015743: Marlboro Menthol Special Select 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter¹	7.89 mm
Ventilation	15%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 2
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: 2020.05.27 13:05:01 -04'00'

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: 2020.05.27 14:00:44 -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:

SE0015736: Benson & Hedges 100's Luxury Box	
Product Name	Benson & Hedges 100's Lights Soft Pack
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	99.5 mm
Diameter¹	7.89 mm
Ventilation	30%
Characterizing Flavor	None
SE0015737: L&M Menthol Box	
Product Name	L&M Menthol Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	84.0 mm
Diameter¹	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 1
SE0015738: Marlboro Menthol Special Select 100's Box	
Product Name	Marlboro Menthol Special Select 100's Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter¹	7.89 mm
Ventilation	15%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 1

SE0015741: L&M Menthol Box	
Product Name	L&M Menthol Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	84.0 mm
Diameter¹	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 2
SE0015742: L&M Menthol Box	
Product Name	L&M Menthol Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	84.0 mm
Diameter¹	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 3
SE0015743: Marlboro Menthol Special Select 100's Box	
Product Name	Marlboro Menthol Special Select 100's Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter¹	7.89 mm
Ventilation	15%
Characterizing Flavor	Menthol
Additional Property	Tipping Paper 2

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On February 28, 2020, FDA received six SE Reports (SE0015736–SE0015738 and SE0015741–SE0015743) from Altria Client Services LLC on behalf of Philip Morris USA Inc. FDA issued an Acceptance letter to the applicant on March 6, 2020.

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 Maria Suarez on March 6, 2020.

The final 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 in SE0015736 is a grandfathered product (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated March 26, 2020, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product in SE0015736 is grandfathered and, therefore is an eligible predicate tobacco product.

The predicate tobacco products in SE0015737–SE0015738 and SE0015741–SE0015743 were determined to be substantially equivalent by FDA under SE0014926, SE0014930, SE0014931, SE0014934 and SE0014935. 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 April 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

A chemistry review was completed by DeLauren McCauley on April 14, 2020.

The 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:

- Cigarette seam adhesive (b) (4) mg/cig, ↑14-15%:
 - (b) (4) (b) (4) (b) (4) mg/cig, ↓47-48%
 - (b) (4) mg/cig, ↑367-377%
 - Presence of defoamer (b) (4) mg/cig
 - Presence of (b) (4) (b) (4) mg/cig
 - Presence of (b) (4) (b) (4) mg/cig
- Tipping adhesive (b) (4) mg/cig, ↑1%): Addition of (b) (4) mg/cig for SE0015736, SE0015738, and SE0015743; (b) (4) mg/cig for SE0015737, SE0015741, and SE0015742



- Tipping adhesive
 - (b) (4) (added; (b) (4) mg/cig)

For all SE Reports, ingredients are added to the cigarette seam adhesive and to the tipping adhesive of the new tobacco products. Collectively, the addition of (b) (4) and complex defoamer in cigarette seam adhesive may increase smoke yields for benzene, acrolein, acetaldehyde, and formaldehyde. However, the testing data for these HPHCs generated under ISO and CI regimens were analytically equivalent between the new and predicate tobacco products. For all SE Reports, none of the reported changes in HPHCs cause the new products to raise different questions of public health from a toxicological perspective. Furthermore, (b) (4) is added to the tipping adhesive. Tipping adhesive is not expected to be burned or be a potential source of thermal degradation leading to the generation of HPHCs. Smokers are not expected to have direct oral or dermal contact with any residual (b) (4) in the tipping adhesive as the glue is bound at the tipping paper seam which is covered by the tipping paper. Therefore, in all SE Reports, the addition of (b) (4) to the tipping adhesive of the new tobacco products is unlikely to cause the new tobacco products to raise different questions of public health from a toxicological perspective.

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

An environmental review was completed by Susana Addo Ntim on March 31, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 15, 2020. The FONSI was supported by an environmental assessment prepared by FDA on April 15, 2020.

6. CONCLUSION AND RECOMMENDATION

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

products do not cause the new tobacco products to raise different questions of public health.

The predicate tobacco product in SE0015736 meets statutory requirements because it was determined that it is a grandfathered tobacco product (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

The predicate tobacco products in SE0015737–SE0015738 and SE0015741–SE0015743 were previously determined to be substantially equivalent by FDA under SE0014926, SE0014930, SE0014931, SE0014934 and SE0014935.

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 SE0015737–SE0015738 and SE0015741–SE0015743 were previously determined to be substantially equivalent by FDA under SE0014926, SE0014930, SE0014931, SE0014934 and SE0014935. Comparison of the new tobacco products to the grandfathered tobacco products (Marlboro Milds 100's Menthol Box in SE0014926, Marlboro Milds 100's Menthol Box in SE0014930, Basic Menthol Soft Pack in SE0014931, Basic Menthol Soft Pack in SE0014934 and Basic Menthol Soft Pack in SE0014935) reveals that the new tobacco products have the following differences in characteristics from the Marlboro Milds 100's Menthol Box, and Basic Menthol Soft Pack, the grandfathered tobacco products:

- Cigarette seam adhesive (b) (4) mg/cig, ↑14-15%):
 - SE0015737, SE0015741, and SE0015742:
 - (b) (4) (↑367%, (b) (4) mg/cigarette)
 - (b) (4) (b) (4) (↓47%, (b) (4) mg/cig)
 - Presence of defoamer (b) (4) mg/cig)
 - Presence of (b) (4) (b) (4) mg/cig)
 - Presence of (b) (4) mg/cig)
 - SE0015738, and SE0015743:
 - (b) (4) (↑377%, (b) (4) mg/cigarette)
 - (b) (4) (b) (4) (↓(b) (4) mg/cig)
 - Presence of defoamer (b) (4) mg/cig)
 - Presence of (b) (4) mg/cig)
 - Presence of (b) (4) mg/cig)
- Tipping adhesive
 - Addition of (b) (4)
 - SE0015737, SE0015741, and SE0015742: (b) (4) mg/cig
 - SE0015738 and SE0015743: (b) (4) mg/cig
- Base Tipping Paper:
 - SE0015737
 - Presence of (b) (4) (b) (4) (↑, (b) (4) mg/cigarette)
 - Removal (b) (4) (↓, (b) (4) mg/cigarette)
 - SE0015738
 - Decrease in (b) (4) (↓64%, (b) (4) mg/cigarette)
 - Increase in (b) (4) (↑211%, (b) (4) mg/cigarette)

- SE0015741
 - Decrease in (b) (4) (↓34%, (b) (4) mg/cigarette)
- SE0015742
 - Decrease in (b) (4) (↓9%, (b) (4) mg/cigarette)
 - Presence of (b) (4) (↑, (b) (4) mg/cigarette)
 - Removal of (b) (4) (↓, (b) (4) mg/cigarette)
- SE0015743
 - Decrease in (b) (4) (↓81%, (b) (4) mg/cigarette)
 - Increase in (b) (4) (↑186%, (b) (4) mg/cigarette)
 - Presence of (b) (4) (↑, (b) (4) mg/cigarette), (b) (4) (↑, (b) (4) mg/cigarette), starch (↑, (b) (4) mg/cigarette), (b) (4) (↑, (b) (4) mg/cigarette)
- Tipping Ink
 - Decrease in (b) (4) (All new to GF comparisons):
 - SE0015737: ↓40%, (b) (4) mg/cigarette
 - SE0015738: ↓32%, (b) (4) mg/cigarette
 - SE0015741: ↓41%, (b) (4) mg/cigarette
 - SE0015742: ↓41%, (b) (4) mg/cigarette
 - SE0015743: ↓25%, (b) (4) mg/cigarette
- Tipping Ink Extender:
 - Removal of (b) (4) (All new to GF comparisons):
 - SE0015737, SE0015741, SE0015742: (b) (4) mg/cigarette
 - SE0015738: (b) (4) mg/cigarette
 - SE0015743: (b) (4) mg/cigarette

The differences in characteristics listed above, other than the differences in cigarette seam adhesive and tipping adhesive, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0015737–SE0015738 and SE0015741–SE0015743. Therefore, these differences do not cause the new tobacco products in SE0015737–SE0015738 and SE0015741–SE0015743 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in cigarette seam adhesive and tipping adhesive between the new tobacco products in SE0015737–SE0015738 and SE0015741–SE0015743 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 SE0015737–SE0015738 and SE0015741–SE0015743 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 SE0015736–SE0015738 and SE0015741–SE0015743, as identified on the cover page of this review.