

Technical Project Lead (TPL) Review: SE0015757

SE0015757: Virginia Slims Superslims Menthol Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98.0 mm
Diameter ¹	5.41 mm
Ventilation	70%
Characterizing Flavor	Menthol
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) order.	

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

Technical Project Lead (TPL):

Digitally signed by Samantha Spindel -S3
Date: 2020.06.03 13:38:53 -04'00'

Samantha Spindel, Ph.D., M.Eng.
CDR, US Public Health Service
Engineering 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: 2020.06.03 13:56:55 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

TABLE OF CONTENTS

1. BACKGROUND	4
1.1. PREDICATE TOBACCO PRODUCTS	4
1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW.....	4
1.3. SCOPE OF REVIEW.....	4
2. REGULATORY REVIEW	4
3. COMPLIANCE REVIEW	4
4. SCIENTIFIC REVIEW	5
4.1. CHEMISTRY.....	5
4.2. ENGINEERING	6
4.3. TOXICOLOGY.....	7
5. ENVIRONMENTAL DECISION.....	9
6. CONCLUSION AND RECOMMENDATION	9

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0015757: Virginia Slims Superslims Menthol Box	
Product Name	Virginia Slims Superslims Menthol 100's Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	98.5 mm
Diameter	5.41 mm
Ventilation	70%
Characterizing Flavor	Menthol

The predicate tobacco product is a combusted, filtered cigarette manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 6, 2020, FDA received an SE Report from Altria Client Services LLC on behalf of Philip Morris USA Inc. FDA issued an Acceptance letter to the applicant on March 16, 2020.

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

A regulatory review was completed by Dyanmond Govan on March 16, 2020.

The review concludes that the SE Report is 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 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 dated April 14, 2020, 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 section 910(a)(2)(A)(i)(II) of the FD&C

Act). The OCE review dated May 11, 2020, concludes that the new tobacco product is in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

A scientific review was completed by the Office of Science (OS) for the following disciplines:

4.1. CHEMISTRY

A chemistry review was completed by Youbang Liu on April 22, 2020.

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

- Changes in tobacco blend
 - 2% increase in (b) (4)
 - 1% increase in (b) (4)
 - 2% increase in (b) (4)
 - 67% increase in (b) (4)
 - Removal of (b) (4)
- Changes in ingredients added to tobacco filler
 - 12% increase in (b) (4)
- Changes in seam adhesive
 - Addition of (b) (4) mg/ (b) (4)
 - Removal of (b) (4) mg/cig (b) (4)
- Changes in plug wrap
 - Addition of (b) (4) mg/cig (b) (4)
- Changes in tipping paper
 - 7% increase in (b) (4)
 - 118% increase in (b) (4)

- Analytically inequivalent HPHCs:
 - Tar (↓26% ISO)
 - Carbon Monoxide (↓51% ISO, ↓31% CI)
 - Acetaldehyde (↓34% ISO, ↓22% CI)
 - Acrolein (↓29% ISO, ↓20% CI)
 - Acrylonitrile (↓30% ISO)
 - Ammonia (↓32% ISO)
 - Benzene (↓31% ISO, ↓17% CI)
 - Benzo[a]pyrene (↓41% ISO, ↓35% CI)
 - 1,3-Butadiene (↓29% ISO, ↓20% CI)
 - Crotonaldehyde (↓52% ISO, ↓27% CI)
 - Formaldehyde (↓39% ISO)
 - Isoprene (↓26% ISO, ↓18% CI)
 - NNK (↓23% ISO)
 - NNN (↓27% ISO)
 - Toluene (↓30% ISO)

The increase of (b) (4) and (b) (4) may result in higher mainstream smoke yields of tar, nicotine, carbon monoxide, NNN (N-nitrosornicotine), NNK (4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone), B[a]P (Benzo[a]pyrene), acetaldehyde, formaldehyde and acrolein. All above mentioned harmful and potentially harmful constituents (HPHCs) decrease in both ISO (International Standard Organization) and CI (Canadian Intense) smoking regimens, which demonstrates that the differences of tobacco blend and (b) (4) in tobacco filler between the new and predicate products do not cause the new tobacco product to raise different questions of public health.

Although ingredient differences in seam adhesive, plug wrap and tipping paper cannot be attributed to specific HPHCs, (b) (4) and (b) (4) (b) (4) have very similar chemical structures and properties, and the plug wrap and tipping paper are not consumed or combusted during smoking. Therefore, the replacement of (b) (4) with (b) (4) (b) (4) in the seam adhesive, the additional (b) (4) in plug wrap, and the increase of (b) (4) and (b) (4) should not cause the new tobacco product to raise different questions of public health.

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 chemistry perspective.

4.2. ENGINEERING

An engineering review was completed by Rashele Moore on April 27, 2020.

The engineering review concludes that the new tobacco product has different characteristics related to product engineering compared to the corresponding predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- Increase in tobacco rod density (12%)
- Increase in total denier (10%)
- Increase in filter pressure drop (7%)
- Decrease in cigarette paper base paper basis weight (51%)
- Decrease in cigarette paper band porosity (25%)
- Increase in cigarette paper porosity (532%)

The new and predicate tobacco products have identical target values and range limits for cigarette diameter, tobacco oven volatiles, denier per filament, filter ventilation, and tipping paper length. In addition, the tobacco cut size target value is identical for the new and predicate tobacco products. The applicant stated the tobacco cut size is a machine setting with only target values; therefore, the lack of range limits for this design parameter does not cause the new product to raise different questions of public health.

The applicant provided the target values and range limits for cigarette length, tobacco filler mass, cigarette paper band width, cigarette band space, filter density, and filter length. Target values and range limits for these design parameters have minimal differences compared to the predicate product, which do not cause the new tobacco product to raise different questions of public health. No additional information is required.

The applicant provided the cigarette paper base paper basis weight, cigarette base paper porosity, and cigarette paper band porosity target values and range limits. The new tobacco product's cigarette paper base paper basis weight and cigarette paper band porosity decrease in comparison to the predicate product. The new tobacco product's cigarette paper porosity increases in comparison to the predicate product, which may reduce smoke constituents. Engineering deferred the evaluation of tar, nicotine and carbon monoxide (TNCO) yields to chemistry to resolve the decrease in cigarette paper base paper basis weight and cigarette paper band porosity and the increase in cigarette paper porosity.

The applicant provided the tobacco rod density, total denier, and filter pressure drop target values and range limits. The new tobacco product's tobacco rod density, total denier, and filter pressure drop increase in comparison to the predicate product. Engineering deferred the evaluation of tar and nicotine yields to chemistry to verify the increase in tobacco rod density, total denier, and filter pressure drop.

Therefore, in this case 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 an engineering perspective.

4.3. TOXICOLOGY

A toxicology review was completed by Daniel W. Beury on April 24, 2020.

The 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. The review identified the following differences:

- Ingredients added or increased in the combusted portion of the cigarette:
 - Ingredients added to tobacco: Increases in (b) (4) and (b) (4)
 - Cigarette paper: additions of (b) (4) and (b) (4)
 - Seam adhesive: replaces (b) (4) with (b) (4), increases the amount of (b) (4) and (b) (4), and uses a new (b) (4)
- Ingredients added or increased to the non-combusted portion of the cigarette:
 - Filter tow and plasticizer: increases in acetone, (b) (4)
 - Plug wrap: addition of (b) (4)
 - Tipping adhesive: addition of (b) (4)
 - Filter seam adhesive: increases in (b) (4)
 - Base tipping paper: additions of (b) (4) and increases in (b) (4)
 - Tipping ink: increases in (b) (4)
- Tobacco blend changes:
 - Increase in (b) (4)
 - Removal of the (b) (4)

The new tobacco product has changes in the tobacco blend and multiple increases and additions of ingredients other than tobacco added to the combustible portion of the cigarette. Removal of the (b) (4) is offset by an increase in (b) (4), and (b) (4) subcomponents. Therefore, the changes to the tobacco blend do not cause the new product to raise different questions of public health from a toxicological perspective.

The new tobacco product has changes in ingredients that constitute the non-combusted subcomponents of the cigarette compared to the predicate tobacco product. There are additions or increases in the filter tow, plasticizer, plug wrap, tipping and filter seam adhesives, base tipping paper, and tipping ink ingredients. Considering these are structural materials associated with the non-combusted portion of a cigarette, the added ingredients are not expected to be burned, volatilized, transferred to mainstream smoke, or to be a potential source of HPHCs for inhalation exposure.

The applicant added or increased ingredients to tobacco, the cigarette paper, and the seam adhesive, which are all included in the combusted portion of the cigarette. The mainstream smoke TNCO as well as select HPHC yields (acetaldehyde, acrolein, acrylonitrile, ammonia, benzene, benzo[a]pyrene, 1,3-butadiene, crotonaldehyde, formaldehyde, isoprene, NNK, NNN, toluene) provided by the applicant were either analytically equivalent or analytically

inequivalent and decreased between the new and predicate tobacco products under both the ISO and CI smoking regimens.

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 toxicological perspective.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Shannon Hanna on April 15, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 21, 2020. The FONSI was supported by an environmental assessment prepared by FDA on April 21, 2020.

6. CONCLUSION AND RECOMMENDATION

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

- Changes in tobacco blend
 - 2% increase in (b) (4)
 - 1% increase in (b) (4)
 - 2% increase in (b) (4)
 - 67% increase in (b) (4)
 - Removal of (b) (4)
- Changes in ingredients added to tobacco filler
 - 12% increase in (b) (4)
 - Increases in (b) (4), and (b) (4)
- Changes in seam adhesive
 - Addition of (b) (4) mg/cig (b) (4)
 - Removal of (b) (4) mg/cig (b) (4)
 - Added (b) (4), increased amount of (b) (4) and (b) (4), and use of a new (b) (4)
- Changes in plug wrap
 - Addition of (b) (4) mg/cig (b) (4)
- Changes in tipping paper
 - 7% increase in (b) (4)
 - 118% increase in (b) (4)
 - Additions of (b) (4), and (b) (4)
- Changes in cigarette paper: additions of (b) (4) and (b) (4)
- Design Parameter Changes
 - Increase in tobacco rod density (12%)
 - Increase in total denier (10%)
 - Increase in filter pressure drop (7%)
 - Decrease in cigarette paper base paper basis weight (51%)
 - Decrease in cigarette paper band porosity (25%)
 - Increase in cigarette paper porosity (532%)
- Ingredients added or increased to the non-combusted portion of the cigarette

- Filter tow and plasticizer: increases in acetone, (b) (4)
- Tipping adhesive: addition of (b) (4)
- Filter seam adhesive: increases in (b) (4)
- Tipping ink: increases in (b) (4)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. There are numerous design parameter changes as well as tobacco blend changes and increased or added ingredients in both the combusted and non-combusted portions of the new tobacco product. The changes to the structural materials in the non-combusted portion of the cigarette are not expected to be burned, volatilized, transferred to mainstream smoke, or to be a potential source of HPHCs for inhalation exposure and thus do not cause the new tobacco product to raise different questions of public health. Although ingredient differences in seam adhesive, plug wrap and tipping paper cannot be attributed to specific HPHCs, (b) (4) and (b) (4) (b) (4) have very similar chemical structures and properties, and the plug wrap and tipping paper are not consumed or combusted during smoking. Therefore, the replacement of (b) (4) with (b) (4) (b) (4) in the seam adhesive, the additional (b) (4) in plug wrap, and the increase of (b) (4) and (b) (4) do not cause the new tobacco product to raise different questions of public health. The increase of (b) (4) and (b) (4) may result in higher mainstream smoke yields. However, all HPHCs tested under both ISO and CI smoking regimens are either analytically equivalent or analytically inequivalent and decreased. As a result, all design changes, tobacco blend changes, and changes in ingredients in the combusted portion of the new tobacco product do not cause the new product to raise different questions of public health. Therefore, the differences in characteristics between the new and predicate product do not cause the new tobacco product to raise different questions of public health.

The predicate tobacco product meets statutory requirements because it was determined that it 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 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 predicate tobacco products are such that the new tobacco product does not 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 the new tobacco product substantially equivalent and made a finding of no significant impact.

An SE order letter should be issued for the new tobacco product in SE0015757, as identified on the cover page of this review.