

Technical Project Lead (TPL) Review: SE0015545

SE0015545: Virginia Slims 120's Menthol Gold Pack Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	119.5 mm
Diameter	7.32 mm
Ventilation	30%
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.	

Technical Project Lead (TPL):

Digitally signed by Kenneth Taylor -S
Date: 2020.01.27 15:57:02 -05'00'

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: 2020.01.28 08:30:44 -05'00'

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

TABLE OF CONTENTS

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

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0015545: Virginia Slims 120's Menthol Gold Pack Box	
Product Name	Virginia Slims Luxury Lights 120's Menthol Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	119.5 mm
Diameter	7.32 mm
Ventilation	30%
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 October 30, 2019, FDA received one SE Report from Altria Client Services LLC, on behalf of Philip Morris USA Inc. FDA issued an Acknowledgment letter to the applicant on November 8, 2019.

Product Name	SE Report
Virginia Slims 120's Menthol Gold Pack Box	SE0015545

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 Samuel Motto on November 08, 2019.

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 November 21, 2019, 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 January 8, 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 Sandra I. Salido on December 18, 2019.

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:

- Composition changes in cigarette paper
 - Addition of (b) (4) (1.7% increase in total (b) (4))
 - 14% increase in (b) (4)
 - 97% increase in (b) (4)
 - 14% decrease in (b) (4)
 - Removal of (b) (4)
- Composition changes in cigarette paper band
 - Addition of (b) (4)
 - Addition of (b) (4)
 - 606% increase in (b) (4)
 - Removal of (b) (4)
- Composition changes in cigarette seam adhesive (and (b) (4))
 - Addition of (b) (4)
 - Addition of (b) (4)
 - 3233% increase in (b) (4)
 - 100% increase in (b) (4)
- Composition changes in filter seam adhesive
 - Addition of (b) (4)
 - 128% increase in (b) (4)
 - 11% decrease in (b) (4)
- Composition changes in tipping adhesive
 - Addition of (b) (4)

The new tobacco product has multiple ingredient differences in cigarette paper, cigarette paper band, cigarette seam adhesive, filter seam adhesive and tipping adhesive. The increases in (b) (4) can affect the smoke yields of harmful and potentially harmful constituents (HPHCs) such as acetaldehyde, formaldehyde, (b) (4), (b) (4) significantly increases in the cigarette paper band, which can affect combustion and result in differences in carbon monoxide smoke yields. However, the submitted International Organization for Standardization (ISO) non-intense and Canadian Intense smoke yields for tar, nicotine, carbon monoxide, carbonyls, volatile organics, benzo-a-pyrene and tobacco-specific nitrosamines are analytically equivalent between the new and predicate tobacco products. Additionally, the increase in total (b) (4) which are (b) (4), should intuitively result in a decrease in puff count and is considered a favorable change. Experimentally, the puff counts are analytically equivalent between the new and predicate tobacco products. The differences in the cigarette seam adhesive, filter seam adhesive and tipping adhesive are for ingredients that comprise less than 0.1% of the weight of the cigarette product and therefore are not anticipated to have measurable effects on smoke chemistry. Additionally, the filter and tipping adhesives are non-combusted components.

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 Raymond L. Williamson on December 12, 2019.

The engineering review concludes that the new tobacco product has different characteristics related to product engineering 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:

- <1% decrease in cigarette paper band space

The cigarette paper band space target specification difference is anticipated to be too small to affect smoke chemistry.

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 an engineering perspective.

4.3. TOXICOLOGY

A toxicology review was completed by Jueichuan C. Kang on December 17, 2019.

The toxicology review concludes that the new tobacco product has different characteristics related to product toxicology 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:

- Composition changes in cigarette paper
 - Addition of (b) (4)
 - 5.1% increase in (b) (4) (paper and band)¹
 - 97% increase in (b) (4)
 - Addition of (b) (4)
 - Addition of (b) (4)
- Composition changes in cigarette paper seam adhesive
 - Addition of (b) (4)
 - Addition of (b) (4)
 - Addition of (b) (4)
 - 3,233% increase in (b) (4)

The toxicology review notes that the mainstream smoke yields of acetaldehyde, formaldehyde, acrolein, benzene, toluene, carbon monoxide, 1,3-butadiene, and benzo- α -pyrene, which are HPHCs that are related to the ingredient changes, are analytically equivalent between the new and predicate tobacco products.

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 Hans Rosenfeldt, Ph.D. for Kimberly Benson, Ph.D. on December 13, 2019. The FONSI was supported by an environmental assessment prepared by FDA on December 12, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Composition changes in cigarette paper
 - Addition of (b) (4) (1.7% increase in (b) (4))
 - 14% increase in (b) (4)
 - 97% increase in (b) (4)
 - 14% decrease in (b) (4)
 - Removal of (b) (4) and (b) (4)
- Composition changes in cigarette paper band
 - Addition of (b) (4)

¹ Total (b) (4) is calculated from the individual amounts of both (b) (4).

- Addition of (b) (4)
- 606% increase in (b) (4)
- Removal of (b) (4)
- Composition changes in cigarette seam adhesive (and (b) (4))
 - Addition of (b) (4)
 - Addition of (b) (4)
 - 3233% increase in (b) (4)
 - 100% increase in (b) (4)
- Composition changes in filter seam adhesive
 - Addition of (b) (4)
 - 128% increase in (b) (4)
 - 11% decrease in (b) (4)
- Composition changes in tipping adhesive
 - Addition of (b) (4)
- <1% decrease in cigarette paper band space

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. Mainstream smoke yields of relevant HPHCs are analytically equivalent for both the new and predicate tobacco products using both ISO non-intense and Canadian Intense smoking regimens. Therefore, the differences in characteristics between the new and predicate products 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 product is 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 these new tobacco products substantially equivalent and made a finding of no significant impact.

An SE order letter should be issued for the new tobacco product in SE0015545, as identified on the cover page of this review.