

**Technical Project Lead (TPL) Review: SE0015287-SE0015289,
SE0015294, SE0015296 and SE0015331**

SE0015287: Virginia Slims Superslims Menthol Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 millimeters (mm)
Diameter	5.41 mm
Ventilation	70%
Characterizing Flavor	Menthol
SE0015288: Virginia Slims Superslims Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter	5.41 mm
Ventilation	70%
Characterizing Flavor	None
SE0015289: Virginia Slims Menthol Gold Pack 120 Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	119.5 mm
Diameter	7.32 mm
Ventilation	30%
Characterizing Flavor	Menthol
SE0015294: Virginia Slims Box	
Package Type	Hard pack
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.32 mm
Ventilation	23%
Characterizing Flavor	None
SE0015296: Merit Blue Pack 100's Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter	7.89 mm
Ventilation	55%
Characterizing Flavor	None

SE0015331: Basic Menthol Box	
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol
Attributes of SE Reports	
Applicant	Philip Morris USA
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: 2019.09.20 09:22:12 -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 Glen D. Jones -S
Date: 2019.09.20 10:37:22 -04'00'

For 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:

SE0015287: 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 millimeters (mm)
Diameter	5.41 mm
Ventilation	70%
Characterizing Flavor	Menthol
SE0015288: Virginia Slims Superslims Box	
Product Name	Virginia Slims Superslims 100's Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98.5 mm
Diameter	5.41 mm
Ventilation	70%
Characterizing Flavor	None
SE0015289: Virginia Slims Menthol Gold Pack 120 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
SE0015294: Virginia Slims Box	
Product Name	Virginia Slims 100's Box
Package Type	Hard Pack
Package Quantity	20 Cigarettes
Length	98 mm
Diameter	7.32 mm
Ventilation	23%
Characterizing Flavor	None

SE0015296: 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
Diameter	7.89 mm
Ventilation	55%
Characterizing Flavor	None
SE0015331: Basic Menthol Box	
Product Name	Basic Menthol Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.89 mm
Ventilation	0%
Characterizing Flavor	Menthol

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On June 28, 2019, FDA received six SE Reports from Altria Client Services LLC, on behalf of Philip Morris USA Inc. FDA issued an Acknowledgment letter to the applicant on July 8, 2019. On July 10, 2019, FDA conducted a telecon to request the applicant provide additional information to identify the predicate tobacco products for SE0015287- and SE0015288. On July 15, 2019, FDA received an amendment containing the requested information (SE0015352)

Product Name	SE Report	Amendments
Virginia Slims Superslims Menthol Box	SE0015287	SE0015352
Virginia Slims Superslims Box	SE0015288	SE0015352
Virginia Slims Menthol Gold Pack 120 Box	SE0015289	None
Virginia Slims Box	SE0015294	None
Merit Blue Pack 100's Box	SE0015296	None
Basic Menthol Box	SE0015331	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 Samuel Motto on July 8, 2019.

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 SE0015287, SE0015288, SE0015289 and SE0015294 are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews dated July 28, 2019 and July 29, 2019, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered and, therefore are eligible predicate tobacco products.¹

The predicate tobacco products in SE0015296 and SE0015331 were determined to be substantially equivalent by FDA under SE0014912 and SE0012338. 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 September 3, 2019 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 Samantha Reilly on August 15, 2019.

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 difference:

- Addition of (b) (4) /cigarette) to the tipping adhesive

As the amount of (b) (4) added is small (b) (4) /cigarette) and tipping adhesive is not expected to be combusted, this change in composition is not expected to affect smoke chemistry including HPHCs. Thus, from a chemistry perspective, the

¹ Addendum reviews were completed on the original Grandfathered reviews on July 30, 2013 and July 22, 2019, to clarify the package type and size for the predicate and new tobacco products. Since the initial grandfather determination on September 24, 2012, was based on a product of that package type and size, the addendum reviews do not change the conclusion of the initial determination.

modifications to the new products in SE0015287-15289, SE0015294, SE0015296, and SE0015331 are minor. 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.

For SE00015296 and SE0015331, because the predicate tobacco products were previously found to be SE by FDA under SE0014912 and SE0012338, respectively, the chemistry review also compared the new tobacco and corresponding grandfathered tobacco products. For the ingredients not certified identical between the new and predicate products, the chemistry review identified only one key difference between the new and grandfathered tobacco products: the addition of (b) (4). Thus, the chemistry review concluded that the comparison of the new and grandfathered tobacco products does not cause the new tobacco products to raise different questions of public health.

Based on the previous TPL reviews for SE0014912 and SE0012338 (under which the current predicate tobacco products were found to be SE as compared to the grandfathered tobacco products), I determined that there are several additional differences between the new and corresponding grandfathered tobacco products in SE00015296 and SE0015331. For SE0015296, I identified following differences between the new and grandfathered tobacco products:

- Addition of (b) (4) /cig) in the tipping adhesive
- (b) (4) decreased 64% in the tipping paper
- (b) (4) increased 211% in the tipping paper
- The amount of ink decreased 31%
- The total cigarette weight decreased 0.09%
- Several minor ingredient additions and increases (less than 1 mg/cigarette) to the tipping paper, inks and ink extenders in the cigarette filter

For SE0015331, I identified following differences between the new and grandfathered tobacco products:

- Addition of (b) (4) /cig) in the tipping adhesive
- Tobacco blend change (decrease in total quantity and different relative quantities of each tobacco type)
- Several minor changes (less than 1 mg/cigarette) to tobacco filler ingredients
- 11% decrease in (b) (4) in cigarette paper
- Addition of (b) (4) in cigarette paper
- 47% decrease in (b) (4) in cigarette seam adhesive
- Several minor changes (less than 1 mg/cigarette) to tipping ink and paper ingredients

However, the additional differences between the new and corresponding grandfathered tobacco products based on the previous TPL reviews do not change the chemistry conclusion. This is because the differences in characteristics listed above, other than the differences in tipping adhesive, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0014912 and SE0012338. Therefore, these differences do not cause the new tobacco products in SE0015296 and SE0015331 to raise different

questions of public health. Additionally, for the same reasons as discussed above, the differences in tipping adhesive between the new tobacco products in SE0015296 and SE0015331 and the grandfathered tobacco products do not cause the new tobacco products to raise different questions of public health. Therefore, when comparing the new tobacco products in SE0015296 and SE0015331 to the grandfathered tobacco products, the new tobacco products do not raise different questions of public health.

4.2. ENGINEERING

An engineering review was completed by Robert Meyer on August 15, 2019.

The engineering review did not identify any differences in characteristics between the new and corresponding predicate tobacco products that could cause the new tobacco products to raise different questions of public health from an engineering perspective.

4.3. TOXICOLOGY

A toxicology review was completed by Prabha Kc on August 15, 2019. An addendum was conducted on August 29, 2019, to correct a typographical error found in the deficiency language in the 1st Toxicology review of SE0015287—SE0015289, SE0015294, SE0015296, SE0015331.

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

- Addition of (b) (4) [REDACTED] /cigarette) in the tipping paper adhesive

The adhesive is bound to the tipping paper seam and thus the smoker is not expected to come into direct contact with any residual (b) (4) [REDACTED] in the tipping adhesive. Further, tipping adhesive is part of the non-combusted portion of a cigarette and is not expected to be burned, or to be a potential source of thermal degradation resulting in the release of HPHCs. Therefore, the addition of [REDACTED] in tipping adhesive does not raise toxicological concerns.

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 August 16, 2019. The FONSI was supported by an environmental assessment prepared by FDA on August 16, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Addition of (b) (4) /cig) to the tipping adhesive

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. For all SE Reports, there is an addition of a small quantity of (b) (4) as a solvent in the tipping adhesive. The toxicology review states that adhesive is bound to the tipping paper seam and thus the smoker is not expected to come into direct contact with any residual (b) (4) in the tipping adhesive. Further, tipping adhesive is part of the non-combusted portion of a cigarette and is not expected to be burned, or to be a potential source of thermal degradation resulting in the release of HPHCs. 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 in SE0015287, SE0015288, SE0015289 and SE0015294 meet statutory requirements because it was determined that they are grandfathered tobacco products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

The predicate tobacco products for SE0015296 and SE0015331 were previously determined to be substantially equivalent by FDA under SE0014912 and SE0012338.

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 SE0015296 and SE0015331 were previously determined to be substantially equivalent by FDA under SE0014912 and SE0012338, respectively. Comparison of the new tobacco product in SE0015296 to the grandfathered product Merit Blue Pack 100's Box in SE0014912 reveals that the new tobacco products have the following differences in characteristics from Merit Blue Pack 100's Box, the grandfathered tobacco product:

- Addition of (b) (4) g/cig) in the tipping adhesive
- (b) (4) decreased 64% in the tipping paper
- (b) (4) increased 211% in the tipping paper
- The amount of ink decreased 31%
- The total cigarette weight decreased 0.09%
- Several minor ingredient additions and increases (less than 1 mg/cigarette) to the tipping paper, inks and ink extenders in the cigarette filter

Comparison of the new tobacco product in SE0015331 to the grandfathered product Basic Menthol Box in SE0012338 reveals that the new tobacco products have the following differences in characteristics from Basic Menthol Box, the grandfathered tobacco product:

- Addition of (b) (4) /cig) in the tipping adhesive
- Tobacco blend change (decrease in total quantity and different relative quantities of each tobacco type)
- Several minor changes (less than 1 mg/cigarette) to tobacco filler ingredients
- 11% decrease in (b) (4) in cigarette paper
- Addition of (b) (4) in cigarette paper
- 47% decrease in (b) (4) in cigarette seam adhesive
- Several minor changes (less than 1 mg/cigarette) to tipping ink and paper ingredients

The differences in characteristics listed above, other than the differences in (b) (4) contained in tipping adhesive, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0014912 and SE0012338. Therefore, these differences do not cause the new tobacco products in SE0015296 and SE0015331 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in (b) (4) between the new tobacco products in SE0015296 and SE0015331 and the corresponding 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 SE0015296 and SE0015331 to the predicate or 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 SE0015287, SE0015288, SE0015289, SE0015294, SE0015296 and SE0015331, as identified on the cover page of this review.