

Technical Project Lead (TPL) Review: SE0015781

SE0015781: Chesterfield Blue Pack Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 millimeters (mm)
Diameter¹	7.89 mm
Ventilation	18%
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Philip Morris USA Inc.
Report Type	Regular
Product Category	Cigarettes
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):

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Date: 2020.06.18 13:35:40 -04'00'

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: 2020.06.18 14:36:32 -04'00'

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0015781: Chesterfield Blue Pack Box	
Product Name	Chesterfield Blue Pack Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter¹	7.89 mm
Ventilation	18%
Characterizing Flavor	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 20, 2020, FDA received an SE Report from Altria Client Services LLC (ALCS) on behalf of Philip Morris USA Inc (PMUSA). On March 25, 2020, FDA issued an Acceptance letter to the applicant.

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 Iqra Javaid on March 25, 2020.

The review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco product in SE0015781 was determined to be substantially equivalent by FDA under SE0015059. Therefore, the predicate tobacco product 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), as required by section 905(j)(1)(A)(i) of the FD&C Act. The OCE review dated May 27, 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 Ruth Ganunis on April 29, 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:

- Cigarette seam adhesive
 - 48% (↓ (b) (4) mg/cigarette) decrease in (b) (4)
 - 379% (↑ (b) (4) mg/cigarette) increase in (b) (4)

For the combusted cigarette seam adhesive ingredients, the decrease in the amount of (b) (4) (b) (4) is anticipated to decrease smoke constituents. The increase in (b) (4) will not adversely affect smoke chemistry. Additionally, all mainstream smoke non-intense International Organization of Standardization (ISO) and Canadian Intense (CI) smoking regimen harmful and potentially harmful constituent (HPHC) yields 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 chemistry perspective.

4.2. TOXICOLOGY

A toxicology review was completed by Pamela Roque on May 7, 2020.

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

- Cigarette seam adhesive:
 - (b) (4) (Added; (b) (4) mg/cigarette)
 - (b) (4) (Added; (b) (4) mg/cigarette)
 - (b) (4) (Added; (b) (4) mg/cigarette)
 - (b) (4) ng/cigarette)
 - (b) (4) ng/cigarette)

- (b) (4) [redacted] ng/cigarette)
- (b) (4) [redacted] ng/cigarette)
- (b) (4) [redacted] ng/cigarette)
- (b) (4) [redacted]
- (b) (4) [redacted] µg/cigarette)
- (b) (4) [redacted]
- (b) (4) [redacted] ng/cigarette)
- Tipping adhesive:
 - (b) (4) [redacted] (Added; (b) (4) mg/cigarette)

Some of the ingredients added to the cigarette seam adhesive may form acrolein, benzene, acetaldehyde, formaldehyde, 1, 3-butadiene, carbon monoxide, and toluene. However, as determined in the chemistry review, the ISO and CI smoking regimen yields of these HPHCs are analytically equivalent between the new and predicate products. Also, since the tipping paper adhesive is a non-combusted component, the addition of (b) (4) [redacted] is not anticipated 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 a toxicology perspective.

5. ENVIRONMENTAL DECISION

An environmental review was completed by William E. Brenner on April 28, 2020.

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on May 1, 2020. The FONSI was supported by an environmental assessment prepared by FDA on May 1, 2020.

6. CONCLUSION AND RECOMMENDATION

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

- Cigarette seam adhesive:
 - (b) (4) [redacted] (Added; (b) (4) mg/cigarette)
 - (b) (4) [redacted] (Added; (b) (4) mg/cigarette)
 - (b) (4) [redacted] (Added; (b) (4) mg/cigarette)
 - (b) (4) [redacted] ng/cigarette)
 - (b) (4) [redacted] ng/cigarette)

- (b) (4) [redacted]
(b) (4) [redacted] ng/cigarette)
 - (b) (4) [redacted]
ng/cigarette)
 - (b) (4) [redacted] ng/cigarette)
 - (b) (4) [redacted] ng/cigarette)
 - (b) (4) [redacted]
(b) (4) [redacted] µg/cigarette)
 - (b) (4) [redacted]
(b) (4) [redacted] ng/cigarette)
 - (b) (4) [redacted] ng/cigarette)
 - (b) (4) [redacted] ng/cigarette)
 - (b) (4) [redacted]
(b) (4) [redacted] ng/cigarette)
 - (b) (4) [redacted] µg/cigarette)
- Tipping adhesive:
 - (b) (4) [redacted] (Added (b) (4) [redacted] mg/cigarette)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. Some of the ingredients added to the cigarette seam adhesive may form acrolein, benzene, acetaldehyde, formaldehyde, 1, 3-butadiene, carbon monoxide, and toluene. However, the ISO and CI smoking regimen yields of these HPHCs are analytically equivalent between the new and predicate products. Also, since the tipping paper adhesive is a non-combusted component, the addition of (b) (4) [redacted] is not anticipated to affect smoke constituents. 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 was previously determined to be substantially equivalent by FDA under SE0015059.

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 product in SE0015871 was previously determined to be substantially equivalent by FDA under SE0015059. Comparison of the new tobacco product to the grandfathered product (Basic Lights Box in SE0015059) reveals that the new tobacco product has the following differences in characteristics from Basic Light Box, the grandfathered tobacco product:

- Cigarette seam adhesive
 - 48 % (b) (4) mg/cig) decrease in (b) (4)
 - 379% (b) (4) mg/cig) increase in (b) (4)
- Base tipping paper
 - 64% (b) (4) mg/cig) decrease in (b) (4)
 - 3% (b) (4) mg/cig) decrease in (b) (4)
 - 211% (b) (4) mg/cig) increase in (b) (4)

The differences in characteristics listed above, other than the differences in tipping paper and tipping adhesive, are the same differences in characteristics identified for the new and grandfathered tobacco product in SE0015059. Therefore, these differences do not cause the new tobacco product in SE0015781 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in tipping paper and tipping adhesive between the new tobacco product in SE0015781 and the grandfathered tobacco product do not cause the new tobacco product to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0015781 to the predicate of grandfathered tobacco products, the new tobacco product does not raise different questions of public health.

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 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 SE0015781, as identified on the cover page of this review.