FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0015535 - SE0015536

SE0015535: Camel Classic Blue	
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	32%
Characterizing Flavor	None
SE0015536: Camel Classic Blue Soft Pack	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	32%
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	R.J. Reynolds Tobacco Company
Report Type	Regular
Product Category	Cigarette
Product Sub-Category	Combusted, Filtered
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Kenneth Taylor -S
Date: 2020.01.13 16:44:51 -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: 2020.01.13 17:01:32 -05'00'

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:

SE0015535: Camel Classic Blue SE0015536: Camel Classic Blue Soft Pack	
Product Name	Camel Light Hard Pack
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	32%
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 October 17, 2019, FDA received two SE Reports from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. FDA issued an Acceptance letter to the applicant on October 25, 2019.

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 Tacheka Bailey on October 25, 2019.

The reviews conclude that the SE Reports are 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 17, 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 products are in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as required by section 910(a)(2)(A)(i)(II)) of the FD&C Act. The OCE review January 8, 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 Youbang Liu on November 20, 2019.

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

- 4% increase in (b) (4) [redacted]; 1% increase in total tobacco
- Removal of monogram ink
- Replacement of the filter tow and tipping paper

The mainstream smoke yields of tar, nicotine and carbon monoxide (TNCO) are analytically equivalent between the new and predicate tobacco products. Therefore, the tobacco blend differences do not cause the new tobacco products to raise different questions of public health. The removal of monogram ink is not anticipated to affect smoke chemistry because the change is less than 0.1% of the total cigarette weight. Finally, both the filter tow and tipping paper are non-combusted components and therefore the change is not anticipated to affect smoke chemistry, which is again supported by the analytically equivalent TNCO results.

Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a chemistry perspective.

4.2. ENGINEERING

An engineering review was completed by Jimin Kim on November 20, 2019.

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

- (b) (4) [redacted] decrease in (b)(4)

(b)(4)

A decrease in (b)(4) may result in less particulate matter and increase TNCO mainstream smoke yields. However, as evaluated in the chemistry review, the mainstream smoke yields of TNCO are analytically equivalent. Accordingly, the decrease in (b)(4) is inconsequential.

Therefore, the differences in characteristics between the new and predicate tobacco products do not 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 Daniel Beury on November 19, 2019.

The toxicology review did not identify any differences in characteristics between the new and predicate tobacco products that could cause the new tobacco products to raise different questions of public health from a toxicology perspective. Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco products to raise different questions of public health related to product toxicology.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson on December 2, 2019. The FONSI was supported by an environmental assessment prepared by FDA on December 2, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- 4% increase in (b) (4); 1% increase in total tobacco
- Removal of monogram ink
- Replacement of the filter tow and tipping paper
- (b) (4) decrease in (b)(4)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The above changes in the tobacco blend and (b)(4) could affect smoke chemistry, whereas the removal of monogram ink and replacement of the filter tow and tipping paper, which are both non-combusted components, should not. However, the mainstream smoke yields of TNCO are analytically equivalent between the new and predicate tobacco products. Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new tobacco products 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 products do 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 products in SE0015535 and SE0015536, as identified on the cover page of this review.