

Technical Project Lead (TPL) Review:

SE0014763 and SE0014764

SE0014763: Camel Crush Menthol	
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	32%
Characterizing Flavor	Menthol
Additional Property	Crushable menthol capsule in filter
SE0014764: Camel Crush Menthol Silver	
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	32%
Characterizing Flavor	Menthol
Additional Property	Crushable menthol capsule in filter
Common Attributes of SE Reports	
Applicant	R.J. Reynolds Tobacco Company
Report Type	Regular
Product Category	Cigarettes
Product Sub-Category	Combusted, Filtered
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Jeannie H. Jeong-Im -S 2018.12.21 11:23:50
-05'00'

Jeannie Jeong-Im, 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)

Deirdre L. Kittner Digitally signed by Deirdre L.
Kittner -S
-S Date: 2018.12.21 14:48:34 -05'00'

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:

SE0014763: Camel Crush Menthol	
Product Name	Camel Light Box with Menthol Capsule
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	32%
Characterizing Flavor	Menthol
Additional Property	Crushable menthol capsule in filter
SE0014764: Camel Crush Menthol Silver	
Product Name	Camel Light Box with Menthol Capsule
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	32%
Characterizing Flavor	Menthol
Additional Property	Crushable menthol capsule in filter

The predicate tobacco product is a combusted filtered cigarette with a crushable menthol capsule manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received two Substantial Equivalence (SE) Reports from RAI Services Company (RAIS) on June 12, 2018 on behalf of R.J. Reynolds Tobacco Company (RJRT). FDA issued Acknowledgement letters on June 18, 2018. In a teleconference on June 27, 2018, FDA requested information for the Environmental Assessment (EA). On July 5, 2018, FDA received an amendment (SE0014805) containing the information. On August 16, 2018, FDA issued an Advice Information (A/I) Request letter. On October 4, 2018, FDA received an amendment (SE0014880) containing a response to the A/I Letter.

Product Name	SE Report	Amendments
Camel Crush Menthol	SE0014763	SE0014805 SE0014880
Camel Crush Menthol Silver	SE0014764	

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 Brandon Rose on June 18, 2018.

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 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 18, 2018 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.

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 dated December 19, 2018, 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

Chemistry reviews were completed by Caroline Agarabi on July 30, 2018 and November 23, 2018.

The final 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 in the new products compared to the predicate product:

- Incorporate Fire Standard Compliant (FSC) cigarette paper
- Incorporate alternative tipping paper
- Possess a filter with an alternate menthol capsule ((b) (4) menthol) and direct menthol application ((b) (4)) to the filter
- Removal of the monogram ink printed on the barrel
- A4% increase in ((b) (4)) due to an increase in the moisture content

((b) (4)) is 4% higher in the new products compared to the predicate product. The applicant states that the dry weight of the ((b) (4)) is identical for both products and the weight difference is related to the moisture level of the tobacco. Therefore, the 4% difference in ((b) (4)) is nominal and does not raise any concerns with respect to product chemistry. This difference in the tobacco blends does not cause the new products to raise different questions of public health.

The new products incorporate FSC cigarette paper while the predicate product was non-FSC paper. The cigarette base paper porosity also increases by 216%. Under ISO and CI smoking regimens, the tar, nicotine, and carbon monoxide (TNCO) went down by 3% - 9%. Therefore, the change of non-FSC to FSC paper, 216% increase in cigarette base paper porosity, and differences in tipping paper does not cause the new products to raise different questions of public health.

The new products possess an alternate capsule for ((b) (4))

((b) (4))

The capsule of the new products contains less menthol compared to the capsule of the predicate product ((b) (4)) cigarette in the new products versus ((b) (4)) cigarette in the predicate product for SE0014763 and SE0014764). The predicate product does not contain menthol in the filter. The filter of the new products has ((b) (4)) cigarette menthol added. In total, the new products contain ((b) (4)) cigarette menthol and the predicate product contains ((b) (4)) cigarette menthol. Under the ISO smoking regimen, mainstream menthol levels for the new products are ((b) (4)) cigarette for both SE0014763 and SE0014764; the predicate product mean menthol mainstream smoke value is ((b) (4)) cigarette. Under the HCl smoking regimen, menthol for the new products are ((b) (4)) cigarette for SE0014763 and ((b) (4)) cigarette for SE0014764; the predicate product mean menthol mainstream smoke value is ((b) (4)) cigarette. Given that the overall amount of menthol in the filter and capsule has decreased in the new products as compared to the overall amount of menthol in the predicate product, and that the mainstream smoke yields for menthol decreased in the new products in all cases in comparison to the predicate product, the difference in values in menthol in the filter and capsule does not cause the new products to raise different questions of public health from a chemistry perspective. 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.

4.2. ENGINEERING

An engineering review was completed by Michael A. Morschauer on July 27, 2018.

The final engineering review concludes that the new tobacco products have different characteristics related to product engineering compared to the corresponding 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 in the new products compared to the predicate product:¹

- Incorporate FSC cigarette paper
- A 216% increase in cigarette base paper porosity

All of the design parameter information indicates that the new and predicate products are similar in engineering design parameter characteristics *except* for a change to FSC cigarette paper and an increase in cigarette base paper porosity. TNCO values can be used to assess the impact of the change to FSC paper and the increase in cigarette base paper porosity. Accordingly, the impact on TNCO yields of the change to FSC cigarette paper and the increase in cigarette base paper porosity was deferred to chemistry. Therefore, for both SE Reports, the new tobacco products do not raise different questions of public health from an engineering standpoint.

4.3. TOXICOLOGY

A toxicology review was completed by Erica Clark on August 1, 2018.

The final toxicology review concludes that the new tobacco products have different characteristics related to toxicology compared to the corresponding 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 in the new products compared to the predicate product:

- A 4% increase in (b) (4) due to an increase in the moisture content
- Incorporate FSC cigarette paper

¹ For both SE Reports, there were no significant engineering product design issues in the 1st scientific round of review. The applicant was requested to provide design parameter specifications and test data for burn rate and tobacco cut width. The applicant chose not to provide the information. However, this information is not required to determine whether the new and predicate tobacco products raise different questions of public health from an engineering perspective.

- Minor ingredient changes/substitutions made to the non-combusted portion of the filter including the addition of (b) (4) (b) (4) (SE0014763 only).
- A 15% increase in (b) (4) in the crushed capsule

There were minor changes in the new products such as a 4% increase in (b) (4) 15% increase in (b) (4) in the crushable capsule, change from non-FSC to FSC paper, (b) (4) mg/cigarette menthol added to the filter, and (b) (4) cig decrease of menthol in the capsule in the filter. These changes are small and are not expected to increase HPHCs. In fact, TNCOs were lower in the new products than the predicate products. Therefore, the differences in characteristics between the new and corresponding predicate tobacco product do not cause the new tobacco products to raise different questions of public health from a toxicology perspective.

4.4. SOCIAL SCIENCE

A social science review was completed by Elisabeth Sherman on August 1, 2018.

The final social science review concludes that the new tobacco products have different characteristics from the corresponding predicate tobacco product, but the differences do not cause the new tobacco products to raise different questions of public health from a social science perspective. The review identified the following differences in the new products compared to the predicate product:

- An “alternative crushable menthol capsule” with a lower quantity of menthol
- A (b) (4) cigarette of menthol applied to the filter

The new and predicate products have a crushable menthol capsule. The new products both have less menthol in the crushable menthol capsule (b) (4) cig less), but they both also have (b) (4) cig menthol added to the filter. This did not increase menthol in mainstream smoke via ISO and CI smoking regimens. 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 social science perspective.

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Shannon Hanna on July 31, 2018 and November 2, 2018.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on December 12, 2018. The FONSI was supported by an environmental assessment prepared by FDA on December 12, 2018.

6. CONCLUSION AND RECOMMENDATION

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

- Incorporate Fire Standard Compliant (“FSC”) cigarette paper
- Incorporate alternative tipping paper
- Possess a filter with an alternate menthol capsule (less (b) (4) cig menthol) and direct menthol application ((b) (4) cig) to the filter
- Removal of the monogram ink printed on the barrel
- A 4% increase in (b) (4)
- A 216% increase in cigarette base paper porosity
- Minor ingredient changes/substitutions made to the non-combusted portion of the filter including the addition of (b) (4) (SE0014763 only).
- A 15% increase in (b) (4) in the crushed capsule

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. TNCOs were provided for the new and predicate products, which showed the values decreased by 3% – 9% for the new products under ISO and CI smoking regimens. Also, the amount of menthol in the capsule decreased by (b) (4) cig in the new products, but (b) (4) cig was added to the filter. The total amount of menthol in the cigarettes in the new and predicate products are similar. Menthol smoke data was provided demonstrating that the amount of menthol under ISO and CI in mainstream smoke was similar for the new and predicate 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 products meet statutory requirements because it was determined that they are grandfathered products (i.e., were 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 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 SE0014763 and SE0014764, as identified on the cover page of this review.