FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0014068 and SE0014069

SE0014068: Camel Crush Classic	
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
SE0014069: Camel Crush Blue	
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	Cigarette
Product Sub-Category	Filtered Combusted
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2018.06.28 13:55:53 -04'00'

Colleen K. Rogers, Ph.D.
Director
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: 2018.06.28 19:27:08 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the same predicate tobacco product for each new tobacco product:

SE0014068: Camel Crush Classic	
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
SE0014069: Camel Crush Blue	
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 manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received two SE Reports on April 28, 2017, and issued Acknowledgement letters on May 8, 2017. FDA issued an Advice/Information Request (A/I) letter on July 13, 2017. On September 8, 2017, FDA received the applicant's response to the A/I letter (SE0014322). FDA issued a Preliminary Finding (PFind) letter on November 28, 2017. On December 22, 2017, FDA received the applicant's response to the PFind letter (SE0014447).

Product Name	SE Report	Amendments
Camel Crush Classic	SE0014068	SE0014322 SE0014447
Camel Crush Blue	SE0014069	SE0014322 SE0014447

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 Nabanita Nag on May 8, 2017.

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 review dated June 7, 2017, 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) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE reviews dated February 27, 2018, and June 15, 2018, conclude 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 Selvin Edwards on June 26, 2017, and October 19, 2017.

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:

- The new tobacco products use Fire Standard Compliant (FSC) cigarette paper while the predicate tobacco product uses non-FSC cigarette paper
- Several cigarette paper ingredients are present at higher levels in the new tobacco products compared to the predicate tobacco product
- [redacted] is higher by 4% in the new tobacco products compared to the predicate tobacco product
- The predicate tobacco product incorporates a printed monogram on the cigarette paper. In contrast, the new tobacco products do not have a printed monogram on the cigarette paper.
- The new tobacco products use white tipping paper while the predicate tobacco product uses a cork-on-white tipping paper

Although (b) (4) [redacted] is increased by 4% in the new tobacco products, the dry weight of the (b) (4) [redacted] is identical for the new and predicate tobacco products. The reported weight

difference is related to the moisture level of the [redacted]. To the extent that this small difference in moisture affects the production of HPHCs, the differences would not be detectable nor affect HPHCs in such way that would cause the new tobacco product to raise different questions of public health. Therefore, the 4% difference in [redacted] is nominal and does not impact product chemistry. There are differences in the tipping paper design and monogram inks of the new tobacco products compared to the predicate tobacco product. I note that the reviewer did not fully describe the differences in monogram inks between the new and predicate tobacco products. The monogram was removed from the new tobacco product in SE0014068 and was moved from the tobacco rod to the tipping paper for the new tobacco product in SE0014069. Since the tipping paper is not combusted during product use and since the monogram ink was removed in SE0014068, these changes do not cause the new tobacco products to raise different questions of public health from a chemistry perspective. The most significant product composition issue identified during scientific review was that both new tobacco products use Fire Standard Compliant (FSC) cigarette paper while the predicate tobacco product uses non-FSC cigarette paper. Thus, several cigarette paper ingredients are present in higher amounts in the new tobacco products compared to the predicate tobacco product, including [redacted] Higher levels of [redacted] in the cigarette paper could reduce the cigarette puff count of the new tobacco products compared to the predicate tobacco product. However, the puff count for the new and predicate tobacco products is the same under the Health Canada Intense machine smoking regimen and only differs by 5% under the International Organization for Standardization (ISO) machine smoking regimen, which is not statistically significant. Further, viewed from an overall public health perspective and based on the information available at this time, the Office of Science (OS) drafted a memorandum[1] describing its current thinking on FSC paper changes, which states that if the only change in a new combusted tobacco product is the change to FSC cigarette paper, the new tobacco product incorporating FSC cigarette paper does not raise different questions of public health compared to the predicate tobacco product incorporating non-FSC cigarette paper. For the new tobacco products subject to this review, while changes were made to the inks and tipping paper in addition to the FSC cigarette paper change, since these changes do not affect the burned portion of the cigarette, these changes would not cause an increase in the production of HPHCs. Similarly, the 4% increase in b) (4) [redacted] is not expected to raise HPHCs. Consequently, the change to FSC cigarette paper does not cause the new tobacco products to raise different questions of public health from a chemistry 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 from a chemistry perspective.

4.2. ENGINEERING

Engineering reviews were completed by Karen Coyne on June 30, 2017, and October 24, 2017.

The final engineering review concludes that the new tobacco products have different characteristics related to product engineering compared to the predicate tobacco product, but

[1] *See* July 17, 2017, memo entitled, "Toxicological Implications of FSC Paper"

the differences do not cause the new tobacco products to raise different questions of public health. The review identified the following differences:

- The new tobacco products incorporate Fire Standard Compliant (FSC) cigarette paper while the predicate tobacco product uses non-FSC paper
- The new tobacco products do not include the printed monogram ink used on the predicate tobacco product
- Increase in puff count (5% in SE0014068 and 4% in SE0014069)
- 12% increase in cigarette paper base paper basis weight
- 58% increase in cigarette paper base paper porosity
- Increase in overall cigarette mass (≤ 1%)
- The new tobacco product in SE0014069 includes white tipping paper while the predicate tobacco product includes cork-on-white tipping paper

The applicant provided targets, range limits, and test data for all relevant design parameters. All of the design parameter information indicates that the new and predicate tobacco products are identical in engineering design parameters except for increases in puff count, cigarette paper base paper basis weight, cigarette paper base paper porosity, and overall cigarette mass. For both SE Reports, the applicant provided the tar, nicotine, and carbon monoxide (TNCO) values for the new and predicate tobacco products. TNCO values can be used to assess the impact of the increases in puff count, cigarette paper base paper basis weight, cigarette paper base paper porosity, and overall cigarette mass. For both SE Reports, the TNCO values of the new tobacco products do not increase substantially compared to those of the predicate tobacco products. In addition, the differences in puff count are not statistically significant.[2] OS' current thinking is that a change from non-FSC to FSC cigarette paper (in the absence of other design or ingredient changes) does not cause a new tobacco product to raise different questions of public health. As explained in section 4.1 of this review, although there are additional changes beyond a change from non-FSC to FSC cigarette paper, for these SE Reports, those changes do not cause the new tobacco products to raise different questions of public health. 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

Toxicology reviews were completed by Ines Pagan June 30, 2017, and October 27, 2017.

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

- The new tobacco products incorporate Fire Standard Compliant (FSC) cigarette paper while the predicate tobacco product uses non-FSC paper

[2] As evaluated in the first chemistry review

- In SE0014068, the printed monogram ink used for the predicate tobacco product has been removed from the cigarette barrel of the new tobacco product
- In SE0014069, the monograph ink used in the predicate tobacco product has been removed from the cigarette barrel (combusted portion) and added to the preprinted tipping paper (non-combusted portion) of the new tobacco product
- TNCO levels (ISO and Canadian Intense) in the new tobacco products are similar to those in the predicate tobacco product

The final review notes that the applicant provided a complete listing of all individual ingredients comprising tobacco and non-tobacco components and structural materials in the new and predicate tobacco products. The most significant product composition issue identified during scientific review was that both new tobacco products use FSC cigarette paper while the predicate tobacco product uses non-FSC cigarette paper. The submitted TNCO data indicate that there are small increases in TNCO levels in the new tobacco products compared to the predicate tobacco product, but the TNCO smoke yields are within measurement variability and, therefore, are not of toxicological concern. 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 toxicology perspective.

4.4. SOCIAL SCIENCE

A social science review was completed by Katherine Margolis on June 21, 2017.

The social science review concludes that the new tobacco products have different characteristics from the 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:

- The predicate tobacco product includes a printed monogram of a camel on the tipping paper and the new tobacco products do not

I note that the reviewer did not fully describe the differences in monogram inks between the new and predicate tobacco products. The monogram was removed from the new tobacco product in SE0014068 and was moved from the tobacco rod to the tipping paper for the new tobacco product in SE0014069. The social science review states that there are limited data on how cigarette design features such as tipping paper can influence consumer perceptions. The reviewer also notes that the tipping paper modifications will not be noticed at the time of purchase, but rather, will be observed after the product has been purchased and opened. Consequently, changes in consumer behavior such as increased initiation or use solely due to tipping paper changes are likely to be minimal. Although not stated in the social science review, the same would be true for the change from cork-on-white to white tipping paper in SE0014069. 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 social science perspective.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on June 28, 2018. The FONSI was supported by an environmental assessment prepared by FDA on June 28, 2018.

6. CONCLUSION AND RECOMMENDATION

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

- A change from non-FSC to FSC cigarette paper, which encompasses the following changes:
  - Increase in several cigarette paper ingredients
  - 12% increase in cigarette paper base paper basis weight
  - 58% increase in cigarette paper base paper porosity
  - Increase in overall cigarette mass (≤ 1%)
  - Increase in puff count (5% in SE0014068 and 4% in SE0014069)
- 4% increase in (b) (4) [redacted]
- Removal of printed monogram of a camel on the tobacco rod (SE0014068)
- Printed monogram of a camel moved from tobacco rod to tipping paper (SE0014069)
- Change from cork-on-white to white tipping paper (SE0014069)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The change to the printed monograms does not cause the new tobacco products to raise different questions of public health because the monogram is either removed entirely, or is moved to the unburned part of the cigarette (tipping paper), which would reduce consumer exposure to any HPHCs resulting from combustion of the monogram inks. The change from cork-on-white to white tipping paper does not cause the new tobacco product in SE0014069 to raise different questions of public health because this change is not noticeable at the time of purchase and would not affect consumer behavior. The small difference in (b) (4) [redacted] does not cause the new tobacco products to raise different questions of public health because the difference is due to a slight difference in moisture. To the extent that this small difference in moisture affects the production of HPHCs, the differences would not be detectable nor affect HPHCs in such a way that would cause the new tobacco product to raise different questions of public health. The major difference between the new and predicate tobacco products is a change from non-FSC to FSC cigarette paper. This change is the basis for the change in cigarette paper ingredients, the increase in cigarette paper base paper basis weight and porosity, and the increase in puff count and overall cigarette mass. As of 2012, all states in the U.S. have enacted laws requiring cigarettes to meet certain fire standards for self-extinction when not being smoked. In order to meet this fire standard, tobacco product manufacturers have used different cigarette paper designs to reduce the burn rate of the product (i.e., FSC cigarette paper). As explained in a July 17, 2017, memorandum,[3] viewed from an overall public health perspective and based on the information available at this time, OS' current thinking is that if the only change in a new combusted tobacco product is the change to FSC cigarette paper, the new tobacco product incorporating FSC cigarette paper does not raise different questions of public health compared to the predicate tobacco product incorporating non-FSC cigarette paper. In this case, since the differences in cigarette paper ingredients, cigarette paper design parameters, puff count, and overall

[3] *See* July 17, 2017, memo entitled, "Toxicological Implications of FSC Paper"

cigarette mass are solely related to the change to FSC cigarette paper, these differences do not cause the new tobacco products to raise different questions of public health. While changes were made to the inks and tipping paper in addition to the FSC cigarette paper change, since these changes were either removal of ink or do not affect the burned portion of the cigarette, these changes would not cause an increase in the production of HPHCs and do not affect the conclusions regarding a non-FSC to FSC cigarette paper change. Thus, OS' current thinking about the change from non-FSC to FSC cigarette paper applies to the new tobacco products. Therefore, the differences in characteristics between the new and 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 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 SE0014068 and SE0014069, as identified on the cover page of this review.