FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0015505

SE0015505: Newport Platinum Blue 100	
Package Type	Box
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.8 mm
Ventilation	15%
Characterizing Flavor	Menthol
Attributes of SE Report	
Applicant	R.J. Reynolds Tobacco Company
Report Type	Regular
Product Category	Cigarette
Product Sub-Category	Combusted, Filtered
Recommendation	
Issue a Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Gloria J. Kulesa -S
Date: 2020.06.30 15:47:55 -04'00'

Gloria Kulesa
Engineering 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: 2020.06.30 16:54:14 -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:

SE0015505: Newport Platinum Blue 100	
Product Name	Newport 100s Soft Pack
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	15%
Characterizing Flavor	Menthol

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On September 19, 2019, FDA received an SE Report (SE0015505) from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. On September 30, 2019, FDA issued an Acceptance letter. On November 27, 2019, FDA issued a Deficiency letter. On April 2, 2020, FDA received the applicant's response (SE0015803).

Product Name	SE Report	Amendment
Newport Platinum Blue 100	SE0015505	SE0015803

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 Nikole Ayala-Agosto on September 30, 2019. The final review concludes that the SE Report is 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 October 22, 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 product is 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 June 1, 2020, concludes that the new tobacco product is 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 Abdur Rafay Shareef on November 8, 2019, and May 21, 2020.

The final 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:

- Lower total tobacco and tobacco blend components in the new tobacco product compared to the predicate tobacco product:
  - ↓ 9% (b) (4) mg/cigarette vs. [redacted] mg/cigarette)
  - ↓ 9% (b) (4) mg/cigarette vs. [redacted] mg/cigarette)
  - ↓ 6% (b) (4) mg/cigarette vs. [redacted] mg/cigarette)
  - ↓ 9% (b) (4) mg/cigarette vs (b) (4) [redacted] mg/cigarette)
  - ↓ 8% (b) (4) mg/cigarette vs. [redacted] mg/cigarette)
  - ↓ 9% (b) (4) mg/cigarette vs. [redacted] mg/cigarette)
- B[a]P yields are lower and equivalent in the new and predicate tobacco products
- Fire Standards Compliant (FSC) cigarette paper vs non-FSC cigarette paper

The SE Report indicated 9% lower total tobacco and 6-9% lower tobacco blend components. Ingredients other than tobacco that were added directly to the tobacco were lower or equal in the new tobacco product compared to the predicate tobacco product. The new and predicate tobacco products differed by the use of FSC cigarette paper for the new tobacco product, replacing non-FSC cigarette paper in the predicate tobacco product. The ingredients and design parameters of the papers used in the new and predicate tobacco products were changed. The applicant submitted tar, nicotine, and carbon monoxide (TNCO) yields which FDA evaluated using a two one-sided t-test. Higher, non-equivalent CO yields (↑19%) were referred to toxicology for evaluation. Several engineering design parameters were changed. The engineering reviewer indicated that B[a]P might be impacted, and a deficiency was communicated to the applicant. The applicant provided B[a]P mainstream (ISO and CI) smoke yields for the new and predicate tobacco products. B[a]P yields were lower and equivalent under both ISO and CI regimens, (3% and 4%, respectively) in the new tobacco product compared to the predicate tobacco product. Thus, no additional information is required for the chemistry reviewer.

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

4.2. ENGINEERING

An engineering review was completed by Michael Morschauser on November 7, 2019.

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

- Tobacco filler mass decreased by 9%
- Addition of cigarette paper bands
- Cigarette paper base paper porosity increased by 25%
- Filter density decreased by 5%
- Filter length increased by 15%
- Tipping paper length increased by 13%

The applicant provided target specifications and upper and lower range limits for the new and predicate tobacco products for overall cigarette length and circumference, tobacco filler mass, tobacco rod density, tobacco moisture, cigarette paper base paper porosity, filter denier per filament, filter total denier, filter length, filter density, filter pressure drop, filter ventilation, and tipping paper length for the new and predicate tobacco products. The applicant provided target specifications and upper and lower range limits for cigarette paper band diffusivity, band width, and band space for the new tobacco product (the predicate tobacco product is not banded).

The new tobacco product has decreased filler mass (9%), increased paper porosity (25%), decreased filter density (5%), and increased filter length (15%) and tipping paper length (13%). The new tobacco product cigarette paper is banded, while the predicate product cigarette paper is not banded. These changes may affect smoke constituent yields and are therefore deferred to chemistry.

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

4.3. TOXICOLOGY

Toxicology reviews were completed by Yanling Chen on November 8, 2019, and May 22, 2020.

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

- The new tobacco product had identical tobacco composition and identical ingredients, but decreased amounts of tobacco filler and ingredients relative to the predicate tobacco product. The new tobacco product had the same type but decreased amount of rod seam adhesive. Monogram ink was removed in the new tobacco product.

- The new tobacco product had an 18.5% (2.5 mg/cig) increase in mainstream smoke ISO yield of CO when compared to the predicate tobacco product.

The applicant submitted measurements for smoke B[a]P yields and a discussion on CO increase. The B[a]P measurements addressed potential effects of changes in cigarette paper and design features on smoke constituents. Considering the new data submitted by the applicant and the specific differences between the new and predicate tobacco products, the observed CO increase is reasonably anticipated as a result of the change from a non-FSC paper in the predicate tobacco product to an FSC cigarette paper in the new tobacco product to meet state-mandated regulations. Based on the totality of the available information and viewed from an overall public health perspective, the benefit of using FSC cigarette paper in the new tobacco product to reduce household fires and personal injuries is anticipated to outweigh any potential increase in health risks from exposure to increased CO, from a toxicological perspective.

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

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Jr., Ph.D. on May 14, 2020. The FONSI was supported by an environmental assessment prepared by FDA on May 14, 2020.

6. CONCLUSION AND RECOMMENDATION

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

- Tobacco filler mass decreased by 9%
- Cigarette paper base paper porosity increased by 25%
- Filter density decreased by 5%
- Filter length increased by 15%
- Tipping paper length increased by 13%
- FSC cigarette paper used versus non-FSC cigarette paper
- Lower total tobacco and tobacco blend components in the new tobacco product compared to the predicate tobacco product 6-9%)
- Lower B[a]P yields that are analytically equivalent in the new and predicate tobacco products
- Same type but decreased amount of rod seam adhesive

- Removed monogram ink in the new tobacco product
- 18.5% increase in mainstream smoke ISO yield of CO when compared to the predicate tobacco product

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. The decreases and increases in the design parameters, the decreases in the tobacco blends and amount of rod seam adhesive, along with the addition of cigarette paper bands, may affect smoke constituent yields, including TNCO and B[a]P. FDA noted that the CO yields increased and were found non-equivalent. The applicant provided smoke yields for B[a]P, which showed a decrease between the new and predicate tobacco products. Considering that the B[a]P decreased, it is reasonable to conclude that the observed smoke CO increase can be attributed to a specific cause, which is the change from non-FSC paper in the predicate tobacco product to FSC cigarette paper in the new tobacco product. 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 tobacco product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

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 this 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 SE0015505, as identified on the cover page of this review.