Technical Project Lead (TPL) Review: SE0015543-SE0015544

SE0015543: ELEMENTS RED 1 ¼	
Package Type	Booklet
Package Quantity	50 Papers
Length	76 millimeters (mm)
Width	44 mm
Characterizing Flavor	None
Additional Property	Off-white "ELEMENTS" watermark
SE0015544: RAW BLACK 1 ¼	
Package Type	Booklet
Package Quantity	50 Papers
Length	76 mm
Width	44 mm
Characterizing Flavor	None
Additional Property	Off-white "RAW" watermark
Attributes of SE Reports	
Applicant	BBK Tobacco & Foods LLP dba HBI International
Report Type	Regular
Product Category	Roll-Your-Own Tobacco Products
Product Sub-Category	Rolling Paper
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Gloria J. Kulesa -S
Date: 2020.07.22 16:16:16 -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: 2020.07.22 16:29:25 -04'00'

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:

SE0015543: ELEMENTS RED 1 ¼	
Product Name	ELEMENTS 1 ¼
Package Type	Booklet
Package Quantity	50 Papers
Length	76 mm
Width	44 mm
Characterizing Flavor	None
Additional Property	Off-white "HBI" watermark
SE0015544: RAWBLACK 1 ¼	
Product Name	ELEMENTS 1 ¼
Package Type	Booklet
Package Quantity	50 Papers
Length	76 mm
Width	44 mm
Characterizing Flavor	None
Additional Property	Off-white "HBI" watermark

The predicate tobacco product is a roll-your-own (RYO) rolling paper manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On October 28, 2019, FDA received SE Reports (SE0015543-SE0015544) from BBK Tobacco & Foods, LLP dba HBI International. On October 31, 2019, FDA received the applicant's response (SE0015551) to the Office of Compliance and Enforcement (OCE) request for predicate tobacco product information. On October 31, 2019, FDA issued an Acceptance letter. On December 27, 2019, FDA issued a Deficiency letter. On April 14, 2020, FDA received the applicant's response (SE0016203) to the Deficiency letter.

Product Name	SE Report	Amendments
ELEMENTS RED 1 ¼	SE0015543	SE0015551 SE0016203
RAWBLACK 1 ¼	SE0015544	

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 Nia C. White on October 30, 2019. The reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

OCE completed their 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 reviews dated November 26, 2019, 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 July 10, 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

Chemistry reviews were completed by Scott Wasdo on December 19, 2019 and June 16, 2020.

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:

SE0015543:

- Increased quantities of (b) (4) (↑ mg, ↑15%), (b) (4) mg, ↑27%), and (b) (4) mg, ↑43%)
- Higher target air permeability, 25%

SE0015543:

- Decreased quantities of (b) (4) mg, ↓12%), (b) (4) mg, ↓12%)
- Higher measured air permeability, 217%
- Larger range between the lower and upper air permeability specifications ((b) (4) CU)

The new and predicate tobacco products differ in ingredient quantities and air permeability. When compared to the predicate tobacco product, the new tobacco product in SE0015543 has higher quantities of the polysaccharide ingredients: (b) (4) (↑ mg, ↑15%), (b) (4) mg, ↑27%), and (b) (4) mg, ↑43%). In contrast, the tobacco product in SE0015544 has lower quantities of (b) (4) mg, ↓12%) and (b) (4)

([redacted] mg, ↓12%) than the predicate tobacco product. The smoke yields of tar, nicotine, and carbon monoxide (TNCO), acetaldehyde, formaldehyde and acrolein in all new tobacco products are analytically equivalent[1] to (or not analytically equivalent and lower than) those of the predicate tobacco product, therefore, these ingredient differences do not cause the new tobacco products to raise different questions of public health from a chemistry perspective. However, the target and measured air permeability, and the allowed tolerance ranges in air permeability provided by the applicant, indicate that significant differences in air permeability may exist between the new and predicate tobacco products. For example, the new tobacco product in SE0015543 has a target air permeability that is 25% higher than that of the predicate tobacco product, and the new tobacco product in SE0015544 has a measured air permeability that is 217% higher than that of the predicate tobacco product. Such differences may lower the temperature and combustion efficiency of the coal in a manner that increases the smoke yields of the production of polyaromatic hydrocarbons (PAHs). The initial SE reports (SE0015543 and SE0015544) lacked information to address this issue and deficiencies for this information were conveyed to the applicant. In response to the Deficiency letter, the applicant submitted smoke yields of B[a]P in test cigarettes fabricated from the new and predicate tobacco products. Smoke yields of B[a]P from the new tobacco product test cigarettes were determined to be analytically equivalent to those of the predicate tobacco test cigarettes. Therefore, the differences in permeability between the new and predicate tobacco products do not cause the new product 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

Engineering reviews were completed by Michael Morschauser on December 12, 2019[2] and James Melchiors on June 4, 2020[3].

The engineering reviews conclude 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 reviews identified the following differences:

SE0015543:

- Paper mass increased by 25%
- Paper porosity increased by 30%

SE0015544:

- Paper mass decreased by 11%
- Upper range limit for paper porosity increased by [redacted] CU

[1] Determined by using a two one sided t-test (TOST).

[2] An addendum review was completed on December 26, 2019 to correct a formatting error in section 2.3. The addendum did not change the conclusion of the December 12, 2019 engineering review.

[3] The engineering review dated June 4, 2020 is for SE0015544.

SE0015543: differences in paper mass (25% increase) and paper porosity (30% increase) were deferred to chemistry for evaluation of any potential effects they may have on smoke chemistry, including TNCO and B[a]P yields.

SE00015544: A difference in paper mass (11% decrease) was deferred to chemistry for evaluation of any potential effects it may have on smoke chemistry, including TNCO yields. The paper porosity upper range limit increased by (b) (4) CU and the test data indicates that the target specification may not adequately characterize the tobacco product. A deficiency was sent to the applicant and the difference was deferred to chemistry for an evaluation of any potential effects it may have on smoke chemistry, including TNCO and B[a]P yields. To satisfy the engineering deficiency, the applicant submitted an amendment with smoke chemistry test results that demonstrated that the new tobacco product has an average B[a]P delivery of 31.0 ng per cigarette which is below the average B[a]P delivery of 33.7 ng per cigarette of the predicate tobacco product.

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 and engineering perspective.

4.3. TOXICOLOGY

Toxicology reviews were completed by Chad Brocker on December 16, 2019 and by Kristen Wurcel on June 24, 2020.

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:

SE0015543

- Increased level of (b) (4) mg/paper; ↑42.5%)
- Addition of (b) (4) mg/paper; added)
- Increased level of (b) (4) mg/paper; ↑27.7%)
- Increased level of (b) (4) mg/paper; ↑15.5%)
- Analytically equivalent yields of acrolein and formaldehyde
- Analytically non-equivalent decreases in acetaldehyde and carbon monoxide

SE0015544

- Analytically equivalent yields of formaldehyde
- Analytically non-equivalent decreases in acetaldehyde, acrolein, and carbon monoxide

SE0015543-SE0015544

- Analytically equivalent yields of B[a]P

In SE0015543, the levels of (b) (4) , and (b) (4) are increased in the new tobacco product compared to the predicate tobacco product. These

ingredients may pyrolyze to form multiple harmful and potentially harmful constituents (HPHCs). However, the applicant reports HPHC yields in the new product that are analytically equivalent or decreased compared to the predicate tobacco product. Therefore, the ingredient increases and additions in SE0015543 do not cause the new tobacco product to raise different question of public health. In SE0015543-SE0015544, the cigarette paper air permeability increases in the new tobacco products compared to the predicate tobacco product. The increased air permeability may reduce the coal temperature in a burning cigarette and increase consumer exposure to PAHs, such as B[a]P. The applicant did not report smoke yields of any PAHs in the first round of review. The increased air permeability in the new tobacco products in SE0015543-SE0015544 may raise different questions of public health and therefore, a deficiency was sent to the applicant. In response to the Deficiency letter, the applicant reported B[a]P yields for the new and predicate tobacco products that were analytically equivalent in the new tobacco products compared to the predicate tobacco product. Therefore, increases in air permeability in the new tobacco products do not raise different questions of public health from a toxicology 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 toxicology perspective.

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Rudaina Alrefai-Kirkpatrick on December 9, 2019.

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D., ATS on May 26, 2020. The FONSI was supported by an environmental assessment prepared by FDA on May 26, 2020.

6. CONCLUSION AND RECOMMENDATION

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

SE0015543

- Increase in (b) (4) (15%), (b) (4) (27%), and (b) (4) (43%)
- Increased target air permeability (25%)
- Paper mass increased by 25%
- Paper porosity increased by 30%
- Increase in (b) (4) (42.5%)
- Addition of (b) (4) (b) (4) mg/paper)
- Analytically equivalent yields of acrolein and formaldehyde
- Analytically non-equivalent decreases in acetaldehyde and carbon monoxide
- Analytically equivalent yields of B[a]P

SE0015544

- Decreased ingredients: (b) (4) (12%) and (b) (4) (12%)
- Increased measured air permeability (217%)

- Larger range between the lower and upper air permeability specifications (b) (4) CU)
- Paper mass decreased by 11%
- Upper range limit for paper porosity increased by (b) (4) CU
- Analytically equivalent yields of formaldehyde
- Analytically non-equivalent decreases in acetaldehyde, acrolein, and carbon monoxide
- Analytically equivalent yields of B[a]P

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. For SE0015543, testing found the increases and addition of the ingredients, the increase in the target air permeability, and the increases in paper mass and porosity resulted in smoke yields of TNCO, acetaldehyde, formaldehyde and acrolein that were analytically equivalent, or not analytically equivalent and lower than, the predicate tobacco product. For SE0015544, testing found the decrease in ingredients, the increase in the measured air permeability and the larger range between the lower and upper air permeability specifications, the decrease in paper mass, and increase in the upper range limit for paper porosity resulted in smoke yields of formaldehyde, acetaldehyde, acrolein, and carbon monoxide that were analytically equivalent or analytically non-equivalent and lower than the predicate tobacco product. 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.

The predicate tobacco product meets the 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 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 SE0015543-SE0015544, as identified on the cover page of this review.