

Technical Project Lead (TPL) Review: SE0015036 - SE0015037

SE0015036: Elements Red Single Wide	
Package Type	Booklet
Package Quantity	100 Papers (two feeds of 50 papers)
Length	70 mm
Width	37 mm
Characterizing Flavor	None
SE0015037: Raw Black Single Wide	
Package Type	Booklet
Package Quantity	100 Papers (two feeds of 50 papers)
Length	70 mm
Width	37 mm
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	BBK Tobacco & Foods LLP dba HBI International
Report Type	Regular
Product Category	Roll-Your-Own
Product Sub-Category	Rolling Paper
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Jeannie H. Jeong-im -S
Date: 2019.07.18 13:45:14 -04'00'

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)

Digitally signed by Matthew R. Holman -S
Date: 2019.07.18 13:49:13 -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:

SE0015036: Elements Red Single Wide	
SE0015037: Raw Black Single Wide	
Product Name	Elements Single Wide Double Feed ¹
Package Type	Booklet
Package Quantity	100 Papers (two feeds of 50 papers)
Length	70mm
Width	37mm
Characterizing Flavor	None

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 December 21, 2018, FDA received two SE Reports from BBK Tobacco & Foods LLP dba HBI International. On December 26, 2018, FDA issued an Acknowledgement letter. On January 3, 2019 (SE0015043) and on January 10, 2019 (SE0015047), FDA received amendments in response to requests from the Office of Compliance and Enforcement (OCE). On March 8, 2019, FDA issued an Advice/Information (A/I) Request letter. On April 24, 2019, FDA received the applicant’s response to the A/I request letter (SE0015203).

Product Name	SE Report	Amendments
Elements Red Single Wide	SE0015036	SE0015043
Raw Black Single Wide	SE0015037	SE0015047
		SE0015203

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these SE Reports.

2. REGULATORY REVIEW

A regulatory review was completed by Nalintip Oldham on December 26, 2018.

The review concluded that the SE Reports are administratively complete.

¹The chemistry reviews incorrectly identified the predicate product as “Elements Red Single Wide Double Feed.” The correct predicate product is “Elements Single Wide Double Feed.”

3. COMPLIANCE REVIEW

OCE completed a review to determine whether the applicant established that the predicate tobacco product is a grandfathered product (i.e., was commercially marketed as of February 15, 2007). The OCE review dated January 22, 2019, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and, therefore, 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 905(j)(1)(A)(i) of the FD&C Act. The OCE review dated July 12, 2019 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 reviews¹ were completed by Selena Russell on February 20, 2019² and June 10, 2019.³

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:

SE0015036

- 25% (9.47 mg) higher paper mass
- 30% higher base paper porosity
- 9% (0.09 g/g paper) lower (b) (4)
- Addition of (0.09 g/g paper) (b) (4)

SE0015037

- 11% (4.39 mg) lower paper mass
- 194% higher base paper porosity upper range limit

The lower paper mass for SE0015037 is expected to decrease smoke constituents and, therefore, does not cause the new tobacco product to raise different questions of public health. However, the increase in paper mass, increase in base paper porosity, and the changes in the ingredients could alter the combustion temperature and collectively may raise TNCO, carbonyls, and benzo[a]pyrene (B[a]P) for SE0015036. The applicant provided mainstream smoke yields for TNCO, acetaldehyde, acrolein, formaldehyde, and B[a]P under the Canadian Intense (CI) regimen for the new and predicate tobacco products. All the TNCO and HPHC yields between the new

² In the 1st chemistry review, SE0015037 was referred to as SE001537 in error on pages 8 and 9. The correct STN is SE0015037.

³ In the 2nd chemistry review, SE0015036 was referred to as SE0015016 in error on page 6. The correct STN is SE0015036.

and predicate tobacco products were analytically equivalent by TOST.⁴ 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 Ryan Andress on February 12, 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 differences:

SE0015036

- 25% higher paper mass
- 30% higher base paper porosity

SE0015037

- 11% lower paper mass
- 194% higher base paper porosity upper range limit

For SE0015037, the decrease in paper mass may reduce smoke constituent yields and does not cause the new tobacco product to raise different questions of public health. The increase in paper mass may increase smoke constituent yields and is deferred to chemistry for HPHC smoke yield evaluation for the new and predicate tobacco products for SE0015036. The increase in base paper porosity may decrease the combustion temperature and lead to an increase in the yield of carbonyls and B[a]P. The increase in base paper porosity is deferred to chemistry for evaluation of the yield of carbonyls and B[a]P for the new and predicate tobacco products. 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 Jueichuan Kang on February 14, 2019⁵ and June 5, 2019.

The final 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 corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health related to product toxicology.

⁴ Two One-Sided T-test (TOST) is a statistical tool that calculates important analytical differences (IADs) using the Horwitz-Thompson equation.

⁵ In the 1st toxicology review, SE0015036 was referred to as SE0016036 in error on page 7. The correct STN is SE0015036.

5. ENVIRONMENTAL DECISION

Environmental science reviews were completed by Mehran Niazi on February 1, 2019 and June 3, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on June 3, 2019. The FONSI was supported by an environmental assessment prepared by FDA on June 3, 2019.

6. CONCLUSION AND RECOMMENDATION

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

SE0015036

- 25% (9.47 mg) higher paper mass
- 30% higher base paper porosity
- 9% (0.09 g/g paper) lower (b) (4)
- Addition of (0.09 g/g paper) (b) (4)

SE0015037

- 11% (4.39 mg) lower paper mass
- 194% higher base paper porosity upper range limit

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The lower paper mass in SE0015037 is expected to decrease smoke constituents and, therefore, does not cause the new tobacco product to raise different questions of public health. However, the increase in paper mass, increase in base paper porosity, and the changes in the ingredients could alter the combustion temperature and collectively may raise TNCO, carbonyls, and B[a]P for SE0015036. All the TNCO and HPHC yields between the new and predicate tobacco products were analytically equivalent by TOST. 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 SE0015036 and SE0015037, as identified on the cover page of this review.