

**Technical Project Lead (TPL) Review: SE0015745-SE0015749**

<b>SE0015745: ELEMENTS 1 ¼</b>	
<b>Package Type</b>	Booklet
<b>Package Quantity</b>	50 Papers
<b>Length</b>	76 millimeters (mm)
<b>Width</b>	44 mm
<b>Characterizing Flavor</b>	None
<b>Additional Property</b>	White, "ELEMENTS" watermark
<b>SE0015746: ELEMENTS 1 ½</b>	
<b>Package Type</b>	Booklet
<b>Package Quantity</b>	33 Papers
<b>Length</b>	78 mm
<b>Width</b>	61 mm
<b>Characterizing Flavor</b>	None
<b>Additional Property</b>	White, "ELEMENTS" watermark
<b>SE0015747: ELEMENTS SW DF</b>	
<b>Package Type</b>	Booklet
<b>Package Quantity</b>	100 Papers
<b>Length</b>	70 mm
<b>Width</b>	37 mm
<b>Characterizing Flavor</b>	None
<b>Additional Property</b>	White, "ELEMENTS" watermark
<b>SE0015748: ELEMENTS THREE HUNDRED 20CT. BOX</b>	
<b>Package Type</b>	Box
<b>Package Quantity</b>	300 Papers
<b>Length</b>	76 mm
<b>Width</b>	44 mm
<b>Characterizing Flavor</b>	None
<b>Additional Property</b>	White, "ELEMENTS" watermark

<b>SE0015749: ELEMENTS 1 ¼ PERFECT FOLD</b>	
<b>Package Type</b>	Booklet
<b>Package Quantity</b>	50 Papers
<b>Length</b>	76 mm
<b>Width</b>	44 mm
<b>Characterizing Flavor</b>	None
<b>Additional Property</b>	White, "ELEMENTS" watermark
<b>Common Attributes of SE Reports</b>	
<b>Applicant</b>	BBK Tobacco & Foods, LLP dba HBI International
<b>Report Type</b>	Regular
<b>Product Category</b>	Roll-Your-Own
<b>Product Sub-Category</b>	Rolling Paper
<b>Recommendation</b>	
Issue Substantially Equivalent (SE) Orders.	

**Technical Project Lead (TPL):**

Digitally signed by Kenneth Taylor -S  
Date: 2020.05.26 13:38:21 -04'00'

Kenneth M. Taylor, 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: 2020.05.26 13:49:31 -04'00'

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

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**BACKGROUND**

**1.1. PREDICATE TOBACCO PRODUCTS**

The applicant submitted the following predicate tobacco products:

<b>SE0015745: ELEMENTS 1 ¼</b>	
<b>Product Name</b>	ELEMENTS 1 ¼
<b>Package Type</b>	Booklet
<b>Package Quantity</b>	50 Papers
<b>Length</b>	76 mm
<b>Width</b>	44 mm
<b>Characterizing Flavor</b>	None
<b>Additional Property</b>	White, "HBI" watermark
<b>SE0015746: ELEMENTS 1 ½</b>	
<b>Product Name</b>	ELEMENTS 1 ½
<b>Package Type</b>	Booklet
<b>Package Quantity</b>	33 Papers
<b>Length</b>	78 mm
<b>Width</b>	61 mm
<b>Characterizing Flavor</b>	None
<b>Additional Property</b>	White, "HBI" watermark
<b>SE0015747: ELEMENTS SW DF</b>	
<b>Product Name</b>	ELEMENTS SW
<b>Package Type</b>	Booklet
<b>Package Quantity</b>	100 Papers
<b>Length</b>	70 mm
<b>Width</b>	37 mm
<b>Characterizing Flavor</b>	None
<b>Additional Property</b>	White, "HBI" watermark
<b>SE0015748: ELEMENTS THREE HUNDRED 20CT. BOX</b>	
<b>Product Name</b>	ELEMENTS 1 ¼
<b>Package Type</b>	Booklet
<b>Package Quantity</b>	50 Papers
<b>Length</b>	76 mm
<b>Width</b>	44 mm
<b>Characterizing Flavor</b>	None
<b>Additional Property</b>	White, "HBI" watermark

<b>SE0015749: ELEMENTS 1 ¼ PERFECT FOLD</b>	
<b>Product Name</b>	ELEMENTS 1 ¼
<b>Package Type</b>	Booklet
<b>Package Quantity</b>	50 Papers
<b>Length</b>	76 mm
<b>Width</b>	44 mm
<b>Characterizing Flavor</b>	None
<b>Additional Property</b>	White, "HBI" watermark

The predicate tobacco products are Roll-Your-Own (RYO) rolling paper manufactured by the applicant.

### 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 2, 2020, FDA received five SE Reports from BBK Tobacco & Foods, LLP dba HBI International. On March 11, 2020, FDA received an amendment (SE0015765) containing the marketing status of the predicate tobacco products for SE0015745 and SE0015748-SE0015749 requested in the teleconference dated March 11, 2020. On March 23, 2020, FDA issued an Acceptance letter to the applicant. On March 31, 2020, FDA received an unsolicited amendment (SE0015795) containing surrogate information for the new tobacco products.

Product Name	SE Report	Amendments
ELEMENTS 1 ¼	SE0015745	SE0015765 SE0015795
ELEMENTS 1 ½	SE0015746	SE0015795
ELEMENTS SW DF	SE0015747	
ELEMENTS THREE HUNDRED 20CT. BOX	SE0015748	SE0015765
ELEMENTS 1 ¼ PERFECT FOLD	SE0015749	SE0015795

### 1.3. SCOPE OF REVIEW

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

### REGULATORY REVIEW

Regulatory reviews were completed by Kim Jordan on March 20, 2020.

The reviews conclude that the SE Reports are administratively complete.

### 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 March 26, 2020, 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), as required by section 905(j)(1)(A)(i) of the FD&C Act. The OCE reviews dated May 11, 2020 conclude that the new tobacco products are in compliance with the FD&C Act.

## SCIENTIFIC REVIEW

Scientific reviews were completed by the Office of Science (OS) for the following disciplines:

### 1.4. CHEMISTRY

A chemistry review was completed by Mona Shrestha on April 19, 2020.

The chemistry review concludes that the new tobacco products have different characteristics related to product chemistry compared to the corresponding predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health. The review identified the following differences:

#### All SE Reports

- Change in watermark design from “HBI” to “ELEMENTS” symbols
- 18% Increase in base paper porosity

#### SE0015748

- Use of (b) (4) tray slider box versus booklet
- Absence of stabilizer
- 300 rolling papers per tray slider versus 50 rolling papers per booklet
- No starting and warning papers
- No magnet on the holder

#### SE0015749

- No magnet on the booklet

The watermarks are different between the new and corresponding predicate tobacco products. Since the watermark is applied by a (b) (4) process, the watermark difference may affect paper porosity, which may lead to changes in smoke chemistry. The new tobacco products have an 18% increase in base paper porosity, which should result in decreases to tar, nicotine, and carbon monoxide (TNCO) yields. Therefore, the watermark change and resulting porosity increase is not a concern. TNCO and other harmful and potentially harmful constituent (HPHC) smoke yields were not provided for the new and corresponding predicate tobacco

products<sup>1</sup>. However, this data is not necessary because the new and corresponding predicate tobacco products have identical ingredients and paper dimensions, which should not adversely affect smoke chemistry. Finally, the new tobacco products have different packaging or containers. However, since the packaging is not used for rolling cigarettes, the differences do not cause concerns.

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.

### 1.5. ENGINEERING

An engineering review was completed by Raymond L. Williamson on April 20, 2020.

The engineering review concludes that the new tobacco products have different characteristics related to product engineering compared to the corresponding predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health. The review identified the following differences:

- 18% increase in base paper porosity

An increase in paper porosity may decrease TNCO yields by increasing air flow into the tobacco column. Engineering deferred evaluation of TNCO obtained from surrogate tobacco products to the chemistry review.

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 an engineering perspective.

### 1.6. TOXICOLOGY

A toxicology review was completed by Thomas Hill on April 20, 2020.

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

- Minor lettering alterations to the crests within a pressure embossed watermark on paper surface

The watermark is applied exclusively using a (b) (4) method; (b) (4) (b) (4).

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<sup>1</sup> The applicant provided TNCO data for surrogate new and surrogate predicate tobacco products, which was not evaluated because sufficient information was not provided to determine whether the surrogate products could represent the tobacco products under review. TNCO data is not needed to evaluate the changes in characteristics of the new tobacco products.

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.

## ENVIRONMENTAL DECISION

An environmental review was completed by Thomas Creaven on March 27, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 21, 2020. The FONSI was supported by an environmental assessment prepared by FDA on April 20, 2020.

## CONCLUSION AND RECOMMENDATION

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

- Change in watermark design from “HBI” to “ELEMENTS” symbols
- 18% increase in base paper porosity

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The watermark is applied using a

(b) (4) method (b) (4)

(b) (4) The increase in paper porosity caused by the watermark change would also decrease TNCO smoke yields by increasing air flow through the burning tobacco column. 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 SE0015745- SE0015749, as identified on the cover page of this review.