

Technical Project Lead (TPL) Review: SE0015403

SE0015403: Elements King Size Slim	
Package Type	Booklet
Package Quantity	32 papers
Length	108 mm
Width	44 mm
Characterizing Flavor	None
Additional Property	Watermark Design "ELEMENTS"
Attributes of SE Report	
Applicant	BBK Tobacco & Foods LLP dba HBI International
Report Type	Regular
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Rolling Paper
Recommendation	
Issue Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Kenneth Taylor -S
Date: 2019.11.04 16:08:30 -05'00'

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: 2019.11.04 17:24:44 -05'00'

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 product:

SE0015403: Elements King Size Slim	
Product Name	Elements King Size Slim
Package Type	Booklet
Package Quantity	33 papers
Length	108 mm
Width	44 mm
Characterizing Flavor	None
Additional Property	Watermark Design "HBI"

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 August 16, 2019, FDA received an SE Report from BBK Tobacco & Foods LLP dba HBI International. On August 21, 2019, FDA issued an Acknowledgement letter to the applicant. On August 27, 2019 (SE0015413), September 11, 2019 (SE0015438), September 12, 2019 (SE0015474), FDA received amendments in response to requests from the Office of Compliance and Enforcement.

Product Name	SE Report	Amendments
Elements King Size Slim	SE0015403	SE0015413 SE0015438 SE0015474

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 Kaylene Charles on August 21, 2019.

The 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 as of February 15, 2007). The OCE review dated September 19, 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), as required by section 905(j)(1)(A)(i) of the FD&C Act. The OCE review dated October 23, 2019 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

A chemistry review was completed by Jiu Ai on September 30, 2019.

The 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:

- Change in watermark size and shape from letters (H, B, and I) to element symbols (earth, water, wind and fire)
- Decrease in rolling paper amount from 33/booklet to 32/booklet
- Addition of a Starter page

The new watermark does not have a quantitatively measured area difference with that of the predicate tobacco product. However, since the watermark is applied by a (b) (4) process, this symbol difference may cause changes in paper porosity, which may lead to changes in smoke chemistry. However, TNCO yields of test cigarettes made from the new and predicate tobacco products are analytically equivalent. Therefore, the change in watermark does not cause the new product to raise different questions of public health. There is also one less rolling paper in the new product compared to the predicate product. This difference results in the user to be able to roll one less cigarette on a per booklet basis. Also, the added starter page in the new tobacco product is not used for rolling cigarettes; but does contact the rolling paper. The applicant provided testing data that showed there is no detectable chemical transfer from the starter page to the rolling papers.

Therefore, the differences in characteristics between the new and predicate tobacco products 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 Drew Katherine on October 4, 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 difference does not cause the new tobacco product to raise different questions of public health. The review identified the following difference:

- Change in watermark shape and size (from “HBI” to the “Elements” symbols).

Although the watermark is different, the target specifications and range limits for base paper porosity are identical for the new and predicate products. The applicant submitted base paper porosity test data average values that do not match the target values, but they are within the range limits 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 product to raise different questions of public health from an engineering perspective.

4.3. TOXICOLOGY

A toxicology review was completed by Ryan M. Haskins on October 4, 2019.

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

- 23% increase in air permeability
- Addition of an inked starting paper

Higher permeability may affect HPHC smoke yields, however the provided TNCO measurements are analytically equivalent between the new and predicate products. Therefore, the increased air permeability of the new tobacco products is not a concern. With respect to the addition of an inked starting paper, the applicant presented data from a LCMS/GCMS study which demonstrated it is unlikely that ink transfers to the rolling papers. Thus, the addition of an inked starting paper is not a concern.

Therefore, the differences in characteristics between the new and predicate tobacco products 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 Kimberly Benson, Ph.D. on

September 30, 2019. The FONSI was supported by an environmental assessment prepared by FDA on September 30, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Change in watermark size and shape from letters (H, B, and I) to element symbols (earth, water, wind and fire)
- Decrease in rolling paper amount from 33/booklet to 32/booklet
- Addition of an inked starter page

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. TNCO yields of cigarettes prepared from the new and predicate tobacco products are analytically equivalent, demonstrating that the increase in air permeability and different watermark in the new tobacco product does not cause concerns. The new tobacco product replaces a rolling paper with an inked starter page. This change is favorable because it results in the consumer being able to prepare fewer cigarettes. While the starter page contains ink, a LCMS/GCMS study supports that ink transfer does not occur from the added starter page to the actual rolling papers in the new tobacco product. Therefore, the differences in characteristics between the new and predicate products do not cause the new tobacco product 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 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 the 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 SE0015403, as identified on the cover page of this review.