Technical Project Lead (TPL) Review: SE0015819 SE0015824

SE0015819: ELEMENTS ROLLS ULTRA THIN SW	
Package Type	Plastic Holder
Package Quantity	1 Sheet
Length	5000 mm
Width	37 mm
Characterizing Flavor	None
Additional Property	White “ELEMENTS” watermark
SE0015820: ELEMENTS ROLLS ULTRA THIN 1 ¼	
Package Type	Plastic Holder
Package Quantity	1 Sheet
Length	5000 mm
Width	44 mm
Characterizing Flavor	None
Additional Property	White “ELEMENTS” watermark
SE0015821: ELEMENTS ROLLS ULTRA THIN 1 ½ KS	
Package Type	Plastic Holder
Package Quantity	1 Sheet
Length	5000 mm
Width	54 mm
Characterizing Flavor	None
Additional Property	White “ELEMENTS” watermark
SE0015822: ELEMENTS REFILLS SW	
Package Type	Box
Package Quantity	20 Sheets
Length	5000 mm
Width	37 mm
Characterizing Flavor	None
Additional Property	White “ELEMENTS” watermark

SE0015823: ELEMENTS REFILLS 1 ¼	
Package Type	Box
Package Quantity	20 Sheets
Length	5000 mm
Width	44 mm
Characterizing Flavor	None
Additional Property	White “ELEMENTS” watermark
SE0015824: ELEMENTS KING SIZE	
Package Type	Booklet
Package Quantity	33 Sheets
Length	106 mm
Width	54 mm
Characterizing Flavor	None
Additional Property	White “ELEMENTS” watermark
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 Charles Feng -S
Date: 2020.08.31 15:03:28 -04'00'

Charles Feng, 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: 2020.08.31 16:04:16 -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:

SE0015819: ELEMENTS ROLLS ULTRA THIN SW	
Product Name	ELEMENTS ROLLS ULTRA THIN SW
Package Type	Plastic Holder
Package Quantity	1 Sheet
Length	5000 mm
Width	37 mm
Characterizing Flavor	None
Additional Property	Off-White “HBI” watermark
SE0015820: ELEMENTS ROLLS ULTRA THIN 1 ¼	
Product Name	ELEMENTS ULTRA THIN RICE SLIM (1 ¼)
Package Type	Plastic Holder
Package Quantity	1 Sheet
Length	5000 mm
Width	44 mm
Characterizing Flavor	None
Additional Property	Off-White “HBI” watermark
SE0015821: ELEMENTS ROLLS ULTRA THIN 1 ½ KS	
Product Name	ELEMENTS ULTRA THIN RICE KS (1 ½)
Package Type	Plastic Holder
Package Quantity	1 Sheet
Length	5000 mm
Width	54 mm
Characterizing Flavor	None
Additional Property	Off-White “HBI” watermark
SE0015822: ELEMENTS REFILLS SW	
Product Name	ELEMENTS ROLLS ULTRA THIN SW
Package Type	Plastic Holder
Package Quantity	1 Sheet
Length	5000 mm
Width	37 mm
Characterizing Flavor	None
Additional Property	Off-White “HBI” watermark

SE0015823: ELEMENTS REFILLS 1 ¼	
Product Name	ELEMENTS ULTRA THIN RICE SLIM (1 ¼)
Package Type	Plastic Holder
Package Quantity	1 Sheet
Length	5000 mm
Width	44 mm
Characterizing Flavor	None
Additional Property	Off-White "HBI" watermark
SE0015824: ELEMENTS KING SIZE	
Product Name	ELEMENTS KS
Package Type	Booklet
Package Quantity	33 Sheets
Length	106 mm
Width	54 mm
Characterizing Flavor	None
Additional Property	White "HBI" watermark

The predicate tobacco products are roll-your-own (RYO) rolling papers manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received SE Reports on April 3, 2020 (SE0015819 and SE0015822), April 5, 2020 (SE0015820, SE0015821 and SE0015823), and April 6, 2020 (SE0015824) from the applicant. FDA issued an Acceptance Letter on April 10, 2020 (SE0015819 - SE0015823), and April 13, 2020 (SE0015824). On April 22, 2020, FDA received the applicant's response (SE0016216) to OCE's information request related to the predicate tobacco products for SE0015820, SE0015821, SE0015823 and SE0015824. On June 2, 2020, FDA issued a Deficiency Letter for all SE Reports. On June 12, 2020, FDA received the applicant's response (SE0016648) to the Deficiency Letter.

Product Name	SE Report	Amendment
Elements Rolls Ultra Thin SW	SE0015819	SE0016648
Elements Rolls Ultra Thin 1 ¼	SE0015820	SE0016216 and SE0016648
Elements Rolls Ultra Thin 1 ½ KS	SE0015821	
Elements Refills SW	SE0015822	SE0016648
Elements Refills 1 ¼	SE0015823	SE0016216 and SE0016648
Elements King Size	SE0015824	

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 Carlos Suarez on April 10, 2020 (SE0015819-SE0015823) and Michael Jokoh on April 13, 2020 (SE0015824). The final reviews conclude that the SE Reports are administratively complete.

3. 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 May 1, 2020 (SE0015819); May 4, 2020 (SE0015820-SE0015823); and May 5, 2020 (SE0015824), 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)), as required by section 905(j)(1)(A)(i) of the FD&C Act. The OCE review dated August 24, 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 Delauren McCauley on May 26, 2020 and July 27, 2020.

The final 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:

- Embossed watermark
  - "Elements" watermark in new tobacco products
  - "HBI" watermark in predicate tobacco products

The applicant submitted information on rolling paper, ingredients, container closure system, and mainstream smoke data for the new and corresponding predicate tobacco products. The ingredient quantities (b) (4) , and (b) (4)) as well as the container closure system are identical between the new and corresponding predicate tobacco

products. However, there is a difference in the embossed watermark: “Elements” watermark in new tobacco products versus “HBI” watermark in predicate tobacco products. The engineering review indicated that this difference may impact the rolling paper base paper porosity, which in turn, may impact tar, nicotine, and carbon monoxide (TNCO) yields. The engineering deferred the evaluation of TNCO to chemistry.

The applicant used a suitable surrogate predicate product to generate mainstream smoke yields under Canadian Intense smoking regimen. The information on the testing protocols and method validation reports used to generate mainstream smoke yields was provided in a tobacco product master file (TPMF), which was reviewed separately by FDA, and the information was determined to be sufficient. The chemistry review evaluated TNCO and other harmful and potentially harmful constituents (HPHC) yields using a two one-sided t-test (TOST) for mean values between the new and surrogate predicate tobacco products. The TOST analysis resulted in analytically nonequivalent decreases in formaldehyde (↓ 21%), nicotine (↓ 10%), and carbon monoxide (↓ 7%). Nitromethane increased by 0.4 µg/cigarette.[1] All other HPHC yields were analytically equivalent. The analytically nonequivalent quantities of the HPHCs and the increase in nitromethane were deferred to toxicology. Because the testing data for TNCO are either analytically equivalent or decreased, the differences in watermark and paper porosity between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different question 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 review was completed by Mohammad Ali on May 21, 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:

- 23% increase in rolling paper base paper porosity in test data

For all SE Reports, the target specifications and range limits for rolling paper length, paper width, base paper basis weight and base paper porosity of the new and the corresponding predicate products are the same except the design of the rolling paper watermarks. For all SE Reports, the applicant provides test data for rolling paper base paper porosity of the new and the corresponding predicate products, which includes quantitative acceptance criteria, parameter units, test data average value, and the minimum and maximum values of the test data. However, the rolling paper base paper porosity test data average value of the new tobacco products is 23% higher than that of the corresponding predicate tobacco products. A

[1] The value for nitromethane in the predicate tobacco product was less than limit of quantitation (< LOQ). Therefore, a TOST analysis was not performed for nitromethane.

change in rolling paper base paper porosity may lead to a change TNCO smoke yields. Therefore, the evaluation of the TNCO for the new and corresponding predicate products is deferred to chemistry to determine whether the new products raise different questions of public health. The chemistry review indicated that there is no increase in TNCO yields.

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.

4.3. TOXICOLOGY

Toxicology review was completed by Daniel Beury on May 22, 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:

- Watermark

For all SE Reports, the new tobacco products have a different watermark compared to the corresponding predicate tobacco products. The applicant indicates that the watermarks are applied only through pressure and no added ingredient is involved in watermark application. Therefore, there is no ingredient change regarding watermark application and the watermark itself is unlikely to cause the new tobacco products to raise different questions of public health from a toxicological perspective.

For all SE Reports, the applicant provided yields of mainstream smoke constituents for the new and a surrogate predicate tobacco product. Chemistry determined that the surrogate tobacco product is an acceptable substitute. The new tobacco products had analytically nonequivalent decreases in carbon monoxide, nicotine, and formaldehyde and an increase in nitromethane as compared to the surrogate predicate tobacco product. Increased nitromethane could expose users to increased cancer risk. However, the potential cancer risk due to increased nitromethane is likely offset by the decreased levels of formaldehyde in the new tobacco products. Therefore, the increased level of nitromethane in the new tobacco products is unlikely to cause the new tobacco products to raise different questions of public health from a toxicological 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 Thomas Creaven on May 8, 2020 and July 8, 2020.

A finding of no significant impact (FONSI) was signed by Luis Valerio Jr., Ph.D., ATS on

August 06, 2020. The FONSI was supported by an environmental assessment prepared by FDA on August 06, 2020.

6. CONCLUSION AND RECOMMENDATION

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

- Embossed watermark
  - "Elements" watermark in new tobacco products
  - "HBI" watermark in predicate tobacco products
- 23% increase in rolling paper base paper porosity in test data

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. There is a difference in the embossed watermark. The engineering review identified a 23% increase in rolling paper base paper porosity in test data, which in turn, may impact TNCO yields. The smoke yield testing data indicate that there is no increase in TNCO yields. However, there is a small increase in nitromethane yield, but this increase is likely offset by a significant decrease in formaldehyde based on the toxicology 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.

The predicate tobacco products meet statutory requirements because it was determined that they are grandfathered tobacco 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 SE0015819 - SE0015824, as identified on the cover page of this review.