# Technical Project Lead (TPL) Review: SE0014893

| SE0014893: RAW King Size Slim 200 | |
|---|---|
| **Package Type** | Box |
| **Package Quantity** | 200 papers |
| **Length** | 108 mm |
| **Width** | 44 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 Tobacco Products |
| **Product Sub-Category** | Rolling Paper |
| **Recommendation** | |
| Issue Substantially Equivalent (SE) order. | |

**Technical Project Lead (TPL):**

Digitally signed by Jeannie H. Jeong-im -S
Date: 2019.05.23 12:58:10 -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: 2019.05.23 14:36:38 -04'00'

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

## TABLE OF CONTENTS

# 1. BACKGROUND

## 1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

| SE0014893: RAW King Size Slim 200 | |
|---|---|
| **Product Name** | ELEMENTS Kingsize Slim |
| **Package Type** | Booklet |
| **Package Quantity** | 33 papers |
| **Length** | 108mm |
| **Width** | 44mm |
| **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 October 17, 2018, FDA received an SE Report from BBK Tobacco & Foods LLP dba HBI International. FDA issued an Acknowledgement letter on October 26, 2018. FDA issued an Advice/Information Request (A/I) letter on December 14, 2018. On November 7, 2018 (SE0014936), November 14, 2018 (SE0014954), November 16, 2018 (SE0014969), November 27, 2018 (SE0014982), December 4, 2018 (SE0015005), December 6, 2018 (SE0015023), January 10, 2019 (SE0015047), FDA received amendments in response to requests from the Office of Compliance and Enforcement. On March 4, 2019, FDA received the applicant's response to the A/I letter (SE0015109).

| Product Name | SE Report | Amendments |
|---|---|---|
| RAW King Size Slim 200 | SE0014893 | SE0014936<br>SE0014954<br>SE0014969<br>SE0014982<br>SE0015005<br>SE0015023<br>SE0015047<br>SE0015109 |

## 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 Nalintip Oldham on October 26, 2018.

The review concludes 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 in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated December 10, 2018, 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) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated April 26, 2019,[1] 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

Chemistry reviews were completed by Megan Mekoli on December 05, 2018, and April 22, 2019.

The final 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:

- 38% (b)(4) greater air permeability
- 7% (b)(4) greater amount of (b)(4)
- 12% (b)(4) greater formaldehyde and 10% (b)(4) greater acetaldehyde smoke yields under Canadian Intense regimen

Increases in air permeability can cause increases in TNCO, PAHs, and carbonyls smoke yields. However, the applicant clarified that the absolute air permeability values of (b)(4) for the new tobacco product and (b)(4) for the predicate tobacco product are very low. Additionally, the applicant provided smoke yields of TNCO, B[a]P, acrolein, acetaldehyde, and formaldehyde from test cigarettes rolled from the new and predicate tobacco products under the Canadian Intense

[1] An addendum review was completed on May 8, 2019, to correct the new tobacco product name. The addendum review does not change the conclusion of the initial compliance with the FD&C Act determination.

(CI) smoking regimen. The smoke from the new tobacco product contained 5% - 13% (2.2 ng/cig – 9 mg/cig) less B[a]P, nicotine, and tar as well as identical quantities of acrolein and carbon monoxide compared to the predicate tobacco product. Lower and identical quantities of B[a]P, nicotine, tar, acrolein, and carbon monoxide do not cause the new product to raise different questions of public health. The smoke from the new tobacco product contained (10%, (b)(4) ) greater acetaldehyde and 12% ((b)(4) ) greater formaldehyde than the predicate tobacco product; however, higher quantities of formaldehyde and acetaldehyde in the new tobacco product fall within the acceptable margin of expected analytical variability from TOST[2] analysis. (b)(4) increased 7%, but that is only an increase of (b)(4) and is not expected to impact HPHCs. Therefore, from a chemistry perspective, the differences in characteristics between the new and predicate products do not cause the new product to raise different questions of public health.

## 4.2. ENGINEERING

Engineering reviews were completed by James Melchiors, on December 04, 2018, and April 25, 2019.

The final engineering review concludes that the new tobacco product has different characteristics related to product engineering 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:

- Package quantity increased from 33 to 200 papers
- Base paper porosity target specification increased from (b) (4) to (b) (4)

Because the increase in base paper porosity may affect smoke constituent yields, particularly carbonyls and B[a]P, the increase in base paper porosity was deferred to chemistry for further evaluation. 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 and engineering perspective.

## 4.3. TOXICOLOGY

A toxicology review was completed by Luis Dasilva on April 25, 2019.

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

- 7% higher (b)(4)

TNCO, B[a]P, acrolein, acetaldehyde, and formaldehyde were reported under the CI smoking regimen. All the smoke data for the new tobacco product falls within the acceptable margin of expected analytical variability from TOST analysis. Therefore, the differences in characteristics

[2] Two One-Sided T-test (TOST) is a statistical tool that calculates important analytical differences (IADs) using the Horwitz-Thompson equation.
[3] Also known as (b)(4)

between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health related to product toxicology.

## 5. ENVIRONMENTAL DECISION

Environmental science reviews were completed by Mehran Niazi on November 28, 2018, and April 10, 2019.[4]

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 25, 2019. The FONSI was supported by an environmental assessment prepared by FDA on April 25, 2019.

## 6. CONCUSION AND RECOMMENDATION

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

- 7% ((b)(4) ) greater amount of (b)(4)
- 20% increase in base paper porosity target specification
- 38% (b)(4) ) greater air permeability
- 12% (b)(4) ) greater formaldehyde and 10% ((b)(4) ) greater acetaldehyde smoke yields under Canadian Intense regimen
- Package quantity has increased from 33 to 200 papers

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. The (b)(4) adhesive for the new tobacco product is 7% (b)(4) ) higher than that of the predicate tobacco product. However, this increase is minor (b)(4) ) relative to the total tobacco product weight and is not expected to significantly affect the yields of HPHCs in MSS. The 20% increase in base paper porosity target specification and 38% higher air permeability in the new product may affect constituent yields. However, the applicant provided TNCO, B[a]P, acrolein, acetaldehyde, and formaldehyde smoke yields under the CI smoking regimen. All the smoke data for the new tobacco product falls within the acceptable margin of expected analytical variability from TOST analysis. Therefore, the differences in characteristics between the new and predicate tobacco products does 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 corresponding 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 SE order letters be issued.

[4] An addendum review was completed on May 3, 2019 to correct the new tobacco product name.

FDA examined the environmental effects of finding this 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 SE0014893 as identified on the cover page of this review.