

Technical Project Lead (TPL) Review: SE0015653

SE0015653: Raw Classic Rolls Single Wide	
Package Type	Cardboard Holder/Box ¹
Package Quantity	1 Roll
Length	5000 mm
Width	37 mm
Characterizing Flavor	None
Additional Property	Watermark design: "RAW"
Attributes of SE Report	
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.	

¹ Applicant refers to package type as both "booklet" and "holder/box" interchangeably throughout submission. Images in the submission show packaging to be a holder/box.

Technical Project Lead (TPL):

Digitally signed by Samantha Spindel -S3
Date: 2020.04.20 09:24:52 -04'00'

Samantha Spindel, Ph.D., M.Eng.
CDR, US Public Health Service
Engineering 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: 2020.04.20 09:59:36 -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:

SE0015653: Raw Classic Rolls Single Wide	
Product Name	Elements Rolls Ultra Thin SW
Package Type	Plastic Holder/Box ¹
Package Quantity	1 Roll
Length	5000 mm
Width	37 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 January 22, 2020, FDA received an SE Report from BBK Tobacco & Foods LLP dba HBI International. FDA issued an Acceptance letter to the applicant on January 29, 2020. On February 4, 2020 (SE0015679), FDA received the applicant’s response to the request for additional information from the Office of Compliance and Enforcement (OCE).

Product Name	SE Report	Amendment
Raw Classic Rolls Single Wide	SE0015653	SE0015679

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific review completed for this SE Report.

2. REGULATORY REVIEW

A regulatory review was completed by Cynthia Colon on January 29, 2020.

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 in the United States other than exclusively in test markets as of

February 15, 2007). The OCE review dated February 11, 2020, 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 April 17, 2020, 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 Rachel Lerebours on March 16, 2020.

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 key differences:

Container closure system and packaging:

- New tobacco product: (b) (4) cardboard holder in (b) (4) cardboard (b) case
- Predicate tobacco product: (b) (4) holder in (b) (4) cardboard case

The applicant provided ingredient information, including ingredients for materials for the packaging and container closure system (CCS), and mainstream smoke data for the new and predicate tobacco products. The ingredient quantities are identical between the new and predicate tobacco products. The CCS in the new tobacco product is composed of a cardboard holder/display case made of (b) (4) material. The predicate tobacco product is composed of a plastic holder made of (b) (4) and housed in a display case made of (b) (4). Cross-contamination between the CCS and the rolling paper is unlikely to occur and as a result, the CCS is not expected to impact the mainstream smoke yields of Harmful and Potentially Harmful Constituents (HPHCs) for the rolling papers in the new and predicate tobacco products. Therefore, the difference in CCS between the new and predicate tobacco products does not cause the new tobacco product to raise different questions of public health.

The applicant used a third-party lab for smoke analysis, who authorized the applicant to reference their Tobacco Product Master File (b) (4). American Spirit RYO tobacco was used to generate mainstream smoke yields of HPHCs for the new and predicate tobacco products under the Canadian Intense (CI) smoking regimen. A two-one-sided t-test (TOST) statistical analysis was performed comparing the mean values between the new and predicate tobacco products. All the HPHC yields were analytically equivalent, including tar, nicotine, and carbon monoxide (TNCO). 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 Pritesh Darji on March 16, 2020.

The 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 key difference:

- Rolling paper base paper porosity (↑20%)

The rolling papers are sold in one long sheet and do not have perforations for individual sheets of paper. The rolling papers are sold on a “per roll” basis (5000 mm long for both the new and predicate tobacco products), which is then subdivided at will by the consumer. Therefore, base paper basis weight is more applicable and individual paper mass is not required in this particular case. The applicant provides identical target specifications and range limits for the new and predicate tobacco products for all design parameters except for rolling paper base paper porosity, which increases and was deferred to chemistry for evaluation of TNCO.

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 Daniel Beury on March 19, 2020.

The toxicology review did not identify any differences in characteristics between the new and predicate tobacco products that could cause the new tobacco product to raise different questions of public health from a toxicological perspective. The applicant provided relevant HPHC measurements for the new and predicate tobacco products and the yields of all mainstream smoke constituents are analytically equivalent. 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 related to product toxicology.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Thomas Creaven on March 4, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on March 23, 2020. The FONSI was supported by an environmental assessment prepared by FDA on March 23, 2020.

6. CONCLUSION AND RECOMMENDATION

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

- Difference in container closure system and packaging
 - New tobacco product: (b) (4) cardboard holder in (b) (4) cardboard (b) case
 - Predicate tobacco product: (b) (4) holder in (b) (4) cardboard case
- Rolling paper base paper porosity (↑20%)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. Although there is a difference in the CCS between the new and predicate tobacco products, cross-contamination between the CCS and the rolling paper is unlikely to occur and as a result, the CCS is not expected to impact the mainstream smoke yields of HPHCs for the rolling papers in the new and predicate tobacco products. Therefore, the difference in the CCS between the new and predicate tobacco products does not cause the new tobacco product to raise different questions of public health. There is an increase in the rolling paper base paper porosity, which can affect the production of TNCO. However, the ingredient quantities of the paper are identical between the new and predicate tobacco products and all HPHC testing demonstrates all smoke yields are analytically equivalent. Therefore, the difference in the rolling paper base paper porosity does not cause the new tobacco product to raise different questions of public health. Therefore, the differences in characteristics between the new and predicate product 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 product 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 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 SE0015653, as identified on the cover page of this review.