FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0014435

SE0014435: RAW ORGANIC 1/2	
Package Type	Booklet
Package Quantity	33 papers
Length	78 mm
Width	61 mm
Characterizing Flavor	None
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 a Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2018.07.31 10:50:58 -04'00'

Colleen K. Rogers, Ph.D.
Director
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: 2018.07.31 11:08:54 -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:

SE0014435: RAW ORGANIC 1/2	
Product Name	ELEMENTS 1/2
Package Type	Booklet
Package Quantity	33 papers
Length	78 mm
Width	61 mm
Characterizing Flavor	None

The predicate tobacco product is roll-your-own rolling paper manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received one SE Report on December 18, 2017, and subsequently issued an Acknowledgement letter on December 27, 2017. On January 9, 2018, FDA requested additional information to complete predicate tobacco product evaluation. On January 12, 2018, FDA received an amendment (SE0014466) containing the information. FDA issued an Advice/Information Request (A/I) letter on March 12, 2018. On May 4, 2018, FDA received the applicant's response to the A/I letter (SE0014715). On June 26, 2018, FDA received an unsolicited amendment (SE0014790) to correct formatting to the applicant's response to the A/I letter (SE0014715).

Product Name	SE Report	Amendments
RAW ORGANIC 1/2	SE0014435	SE0014466 SE0014715 SE0014790

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 Lynn Oldham on December 27, 2017.

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 January 24, 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 July 12, 2018, 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 Abdur-rafay Shareef on February 16, 2018, and June 18, 2018.

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 difference:

- 4% decrease in paper mass (weight per unit)

The new and predicate tobacco products contain identical ingredients. The difference between the new and predicate tobacco products is a change to the watermark on the paper. The watermark is applied via the 'dandy roll process,' which is an embossing technique and does not result in a change in paper ingredients. Although the weight per unit of product for the new tobacco product (64.23 mg) is 4% lower than that of the predicate tobacco product (66.61 mg), all ingredients are at the same concentrations on a per gram of product basis. Therefore, the difference in characteristics between the new and predicate tobacco products does not cause the new tobacco product to raise different questions of public health from a chemistry perspective.

4.2. ENGINEERING

Engineering reviews were completed by Yan Sun on February 23, 2018, and by Robert Meyer on June 21, 2018.

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:

- 4% decrease in paper mass
- 4% decrease in base paper basis weight
- 20% increase in base paper air permeability (porosity)
- Different product name and packaging graphics[1]

The new and predicate tobacco products have identical length, width, and ingredients, so the differences in paper mass, base paper basis weight, and base paper air permeability are due to changes in the embossing of the watermark on the paper. The 4% decrease in paper mass and base paper basis weight are minor and do not cause the new tobacco product to raise different questions of public health. The 20% increase in base paper air permeability is acceptable from an engineering perspective because an increase in cigarette paper permeability reduces user exposure to smoke constituents. The change in product name and packaging graphics are not changes that are evaluated under the SE pathway and were not evaluated. 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.

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Rudaina Alrefai-Kirkpatrick on March 6, 2018, and June 25, 2018.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on July 26, 2018. The FONSI was supported by an environmental assessment prepared by FDA on July 26, 2018.

6. CONCLUSION AND RECOMMENDATION

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

- 4% decrease in paper mass
- 4% decrease in base paper basis weight
- 20% increase in base paper air permeability

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. The new and predicate tobacco products have identical length, width, and ingredients, so the differences in paper mass, base paper basis weight, and base paper air permeability are due to changes in the embossing of the watermark on the paper. Although there is a 4% decrease in paper mass and base paper basis weight, all ingredients are at the same concentrations on a per gram of product basis and do not cause the new tobacco product to raise different questions of public health. The 20% increase in base paper air

[1] Although a difference in tobacco product name and packaging was noted by the engineering reviewer, those differences were not part of the scientific evaluation for this tobacco product.

permeability does not cause the new tobacco product to raise different questions of public health because an increase in cigarette paper permeability reduces user exposure to smoke constituents. 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 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 SE0014435, as identified on the cover page of this review.