Technical Project Lead (TPL) Review: SE0015089

SE0015089: RAW ORGANIC SINGLE WIDE SINGLE WINDOW	
Package Type	Booklet[1]
Package Quantity	50 sheets
Length	70 mm
Width	37 mm
Characterizing Flavor	None[2]
Attributes of SE Report	
Applicant	BBK Tobacco & Foods LLP d/b/a HBI International
Report Type	Regular Product Quantity Change
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Rolling Paper
Recommendation	
Issue a Substantially Equivalent (SE) order.	

[1] Although not part of the container closure system, I note that the predicate tobacco product is sold in a package containing 50 50-sheet booklets whereas the new tobacco product is sold in a package containing 25 100-sheet booklets.

[2] As provided by the applicant's certification statement. For product quantity change SE Reports, FDA does not conduct substantive scientific review to evaluate the information contained in the applicant's certification statement.

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2019.05.16 10:25:00 -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: 2019.05.16 10:52:37 -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:

SE0015089: RAW ORGANIC SINGLE WIDE SINGLE WINDOW	
Product Name	RAW ORGANIC SINGLE WIDE DOUBLE WINDOW[3]
Package Type	Booklet
Package Quantity	100 sheets
Length	70 mm
Width	37 mm
Characterizing Flavor	None[2]

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On February 20, 2019, FDA received one SE Report from BBK Tobacco & Foods LLP d/b/a HBI International. FDA issued an Acknowledgement letter to the applicant on February 27, 2019. No amendments were submitted.

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

Regulatory reviews were completed by Kaylene Charles on February 27, 2019, and May 15, 2019.

The reviews conclude that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco product was determined to be substantially equivalent by FDA under SE0002390. Therefore, the predicate tobacco product is an eligible predicate tobacco product.

The Office of Compliance and Enforcement (OCE) 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, concludes that the new tobacco product is in compliance with the FD&C Act.

[3] The name of the predicate tobacco product in the SE order (October 3, 2017) is listed as "RAW Organic SW Double".

4. SCIENTIFIC REVIEW

Scientific review was not initiated by the Office of Science (OS) because the product characteristics of the new and predicate tobacco products are identical except for a change in product quantity. OS prepared a memorandum[4] summarizing its current thinking on product quantity changes. With respect to product quantity decreases, even though some of the currently available scientific evidence is specific to tobacco products, the studies do not separate out the effect of reduced price from size on consumption or initiation. Thus, based upon the currently available science and CTP's experience in reviewing SE Reports, from a social science perspective, product quantity changes do not cause new tobacco products to raise different questions of public health. Therefore, scientific review is unnecessary.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Mehran Niazi on March 28, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 22, 2019. The FONSI was supported by an environmental assessment prepared by FDA on April 22, 2019.

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and predicate tobacco products are identical except for a change in product quantity from 100 to 50 rolling papers per booklet (50% decrease).

The OS memorandum[4] concludes that based on OS' experience and the currently available evidence, the difference in product quantity does not cause the new tobacco product to raise different questions of public health. I concur with this conclusion.

The predicate tobacco product was previously determined to be substantially equivalent by FDA under SE0002390.

Where an applicant supports a showing of SE by comparing the new tobacco product to a tobacco product that FDA previously found SE, in order to issue an SE order, FDA must find that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act).

The predicate tobacco product in SE0015089 was previously determined to be substantially equivalent by FDA under SE0002390. Comparison of the new tobacco product to the grandfathered product (RAW 1 and ¼ Box 24) reveals that the new tobacco product has the following differences in characteristics from RAW 1 and ¼ Box 24, the grandfathered tobacco product:

- 56% increase in the number of sheets per booklet
- Changes in booklet package dimensions
- 8% decrease in paper length
- 16% decrease in paper width
- Lower ingredient quantities (because of smaller paper dimensions)

[4] *See* memorandum on product quantity changes, dated December 7, 2017.

- 27% decrease in paper mass
- 18% increase in base paper basis weight
- 30% increase in base paper porosity
- Decreased TNCO yields under Canadian Intense smoking regimen
- Decreased carbonyl yields under Canadian Intense smoking regimen

As discussed in section 4 above, the difference in product quantity (number of sheets per booklet) between the new tobacco product in SE0015089 and the grandfathered tobacco product do not cause the new tobacco product to raise different questions of public health. Additionally, the differences in characteristics listed above, other than the differences in product quantity, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0002390. Therefore, these differences do not cause the new tobacco product in SE0015089 to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0015089 to the predicate or grandfathered tobacco product, the new tobacco product does not raise different questions of public health.

The new tobacco product is currently in compliance with the FD&C Act.

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 SE0015089, as identified on the cover page of this review.