FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review:

SE0014036

SE0014036: OCB XPERT 1 1/4	
Package Type	Booklet
Package Quantity	32 papers
Length	77 mm
Width	44 mm
Characterizing flavor	None
Common Attributes of SE Reports	
Applicant	Republic Tobacco, LP
Report Type	Regular
Product Category	Roll-Your-Own
Product Sub-Category	Rolling Paper
Recommendation	
Issue Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Todd Cecil Digitally signed by Todd Cecil
Date: 2018.04.05 18:50:35 -04'00'

Todd Cecil, Ph.D.
Associate 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: 2018.04.05 19:19:39 -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:

SE0014036: OCB Organic Hemp King Size Slim	
Product Name	OCB Organic Hemp King Size Slim
Package Type	Booklet
Package Quantity	32 papers
Length	109 mm
Width	44 mm
Characterizing flavor	None

The predicate tobacco product is a roll-your-own (RYO) manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

FDA received this SE Report on April 18, 2017, and sent an Acknowledgement letter on May 26, 2017. FDA issued an Advice/Information Request (A/I) letter to the applicant on August 10, 2017. In response, the applicant submitted amendment SE0014351, which FDA received on September 26, 2017. FDA issued a Preliminary Finding letter on December 14, 2017. In response, the applicant submitted amendment SE0014459, which FDA received on January 5, 2018.

Product Name	SE Report	Amendments
OCB XPERT 1 1/4	SE0014036	SE0014351
		SE0014459

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

An acceptance review was completed by Sarah Webster on May 26, 2017.

The final review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco product in SE0014036 was determined to be substantially equivalent by FDA under SE0003298. Therefore, this product 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 2, 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 Scott Wasdo on July 24, 2017 and November 3, 2017.

The final chemistry review concludes that the new tobacco product has different characteristics related to product composition 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 issue related to product composition:

- The new product has (b) (4) less (b) (4) than the predicate product.

The reduction in the amount of (b) (4) in the new tobacco product is expected to contribute to a reduction in the amount of tar and carbon monoxide in the cigarette smoke. The applicant provided information to demonstrate that a cigarette manufactured using the new tobacco product contains less tobacco and generates lower quantities of HPHCs, including TNCOs, than a predicate tobacco product cigarette manufactured using the same tobacco. 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 reviews were completed by Yan Sun on July 20, 2017 and November 16, 2017.

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

- Decrease in cigarette paper length
- Decrease in cigarette paper mass
- Increase in base paper porosity

A decrease in paper length would lead to a reduction in the amount of tobacco available to be burned, and therefore a reduction in HPHC exposure by a user. The decrease in RYO paper mass would most likely result in a decrease in smoke constituent yields. The increase in base paper porosity leads to reductions in the tar yields and the amount of tobacco consumed during a single puff. 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 related to product design.

4.3. TOXICOLOGY

Toxicology reviews were completed by Yanling Chen on August 1, 2017.

The final toxicology review concludes that the new tobacco product has different characteristics related to toxicology compared to the corresponding predicate tobacco product but the differences do not cause the new tobacco products to raise different questions of public health. The review identified the following issues related to toxicology:

- None

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 related to toxicology.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 5, 2018. The FONSI was supported by an environmental assessment prepared by FDA on April 5, 2018.

6. CONCLUSION AND RECOMMENDATIONS

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

- The new product has (b) (4) less (b) (4) than the predicate product.
- Decrease in cigarette paper length
- Decrease in cigarette paper mass
- Increase in base paper porosity

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. The decrease in (b) (4) may lead to a reduction in the HPHC in the smoke. The reduction in (b) (4) is caused by the smaller paper length and paper mass. The smaller size of the new tobacco product will also reduce the amount of tobacco used to prepare a cigarette from the tobacco product, thereby reducing HPHCs further. The increase in base paper porosity may change the TNCO yields in the smoke of cigarettes prepared with the new tobacco product. The applicant has prepared test cigarettes from the new and predicate tobacco products and the reported results demonstrate a reduction in the TNCOs and HPHCs in the new tobacco product compared to the predicate tobacco product. Therefore, the differences in characteristics between the new and corresponding predicate products do not cause the new tobacco products to raise different questions of public health.

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 was determined to be substantially equivalent by FDA under SE0003298. A comparison of the new tobacco product to the grandfathered product presented in SE0003298 indicates substantive relative (percentage) changes in (b) (4) content, but no substantive relative changes to other ingredients or product design characteristics. The lower content of (b) (4) and (b) (4) in the new tobacco product may result in decreases in TNCO and B[a]P when compared to the grandfathered tobacco product. Therefore, the decreases in (b) (4) and (b) (4) content do not cause the new tobacco product to raise different question of public health when compared to the grandfathered tobacco product. The new tobacco product contains higher levels of (b) (4) and (b) (4) than the predicate tobacco product and the grandfathered tobacco product. A substantial increase in (b) (4) or (b) (4) may lead to an increase HPHC content, specifically in acetaldehyde, formaldehyde, and acrolein. The applicant did not provide carbonyl measurements for the grandfathered tobacco product either as a component of the SE Report for SE0003298 or as a component of the SE Report for SE0014036. However, the relative change in the amount of (b) (4) and (b) (4) between the new tobacco product and the predicate tobacco product is larger than the relative change between the new and grandfathered tobacco products. Further, the absolute amount of each of these additives is small enough that it does not raise concerns from a chemistry perspective. In addition, the applicant reports that the new tobacco product contains lower acetaldehyde, formaldehyde, and acrolein levels that the predicate tobacco product. The differences in (b) (4) and (b) (4) between the new and grandfathered tobacco products, do not cause the new tobacco product to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0014036 to the predicate or grandfathered tobacco products, 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. In addition, all of the scientific reviews conclude that the differences between the new and predicate tobacco product is 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 SE0014036, as identified on the cover page of this review.