FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0013972 and SE0013973

SE0013972: OCB Virgin 1-1/4	
Package Type	Booklet
Package Quantity	50 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None
SE0013973: OCB Virgin Slim	
Package Type	Booklet
Package Quantity	32 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Republic Tobacco, LP
Report Type	Regular
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Cigarette Rolling Papers
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2018.04.27 10:16:12 -04'00'

Colleen K. Rogers, Ph.D.
Director
Division of Product Science
Office of 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: 2018.04.27 10:19:32 -04'00'

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0013972: OCB Virgin 1-1/4	
Product Name	OCB Organic Hemp 1-1/4 Size
Package Type	Booklet
Package Quantity	50 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None
SE0013973: OCB Virgin 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 products are roll-your-own (RYO) cigarette rolling papers manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 14, 2017, FDA received two SE Reports from Republic Tobacco, LP. FDA issued an Acknowledgement letter to the applicant on March 21, 2017. FDA issued an Advice/ Information Request (A/I) letter on June 7, 2017. The applicant submitted a response (SE0014219) on July 28, 2017. FDA issued a Preliminary Finding letter on October 20, 2017. The applicant submitted a response (SE0014397) on November 6, 2017. When the new tobacco products in SE0013972 and SE0013973 were initially compared to the grandfathered tobacco products, discrepancies were identified in the applicant's description of the composition of the predicate tobacco products in SE0013972 and SE0013973 (i.e., the products the applicant identified as being previously found substantially equivalent in SE0003299 and SE0003298) and the description of the new tobacco products, which received SE orders, in SE0003299 and SE0003298.[1] FDA issued an A/I letter on February 2, 2018, asking for clarification of the discrepancies in product composition. The applicant submitted a response (SE0014503) on February 7, 2018.

[1] *See* February 2, 2018, Memo to File

Product Name	SE Report	Amendments
OCB Virgin 1-1/4	SE0013972	SE0014219 SE0014397 SE0014503
OCB Virgin Slim	SE0013973	

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these SE Reports.

2. REGULATORY REVIEW

A regulatory review was completed by William Spears on March 21, 2017.

The review concludes that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco products in SE0013972 and SE0013973 were determined to be substantially equivalent by FDA under SE0003299 and SE0003298, respectively. Therefore, the predicate tobacco products are eligible predicate tobacco products.

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the new tobacco products are 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 reviews dated January 22, 2018, and April 9, 2018, conclude that the new tobacco products are 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 Stephanie Daniels on May 10, 2017, and September 14, 2017, and by Salome Bhagan on December 26, 2017.

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

- 15% decrease in [redacted]
- Change from [redacted] (SE0013972) or [redacted] (SE0013973) to [redacted]
- Addition of [redacted] (SE0013972) or [redacted] (SE0013973) mg/rolling paper of [redacted]

- 13% decrease in (b) (4)
- 33% decrease in (b) (4) (SE0013973)
- 33% (SE0013972) or 25% (SE0013793) decrease in (b) (4)
- 16% (SE0013972) or 17% (SE0013793) decrease in (b) (4)

Although the new and predicate tobacco products are cigarette rolling papers that contain no tobacco, pyrolysis of (b) (4) can impact the smoke chemistry of rolling papers. To address the changes in ingredients, including the addition of (b) (4), the applicant submitted HPHC data (acetaldehyde, formaldehyde, acrolein, and benzene) generated from test cigarettes made using the new and corresponding predicate tobacco products and the same commercial tobacco filler. Per test cigarette, each HPHC tested was decreased in the new tobacco product compared to the corresponding predicate tobacco product with the exception of formaldehyde. Formaldehyde was increased 14% in SE0013972; however, this difference was not statistically significant. The applicant also submitted tar and carbon monoxide smoke yields. These data showed no change or only minor increases in the new tobacco product compared to the corresponding predicate tobacco product, which are within the variability of the method. The other ingredient changes (decreases in (b) (4)) are not expected to lead to an increase in HPHC yields, and the submitted HPHC data support this. 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 Tiffany Petty on May 11, 2017, and by Yan Sun on September 8, 2017.

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

- 2900% increase in base paper porosity
- 14% decrease in base paper basis weight
- 14% decrease in paper mass

The applicant provided all of the target specifications, upper and lower range limits, and test data for the applicable design parameters. The engineering review found that given the likelihood that the increase in base paper porosity reduces the tar yields and the amount of tobacco consumed during a single puff, that difference does not cause the new tobacco products to raise different questions of public health. As noted in the chemistry review, the applicant submitted tar yields, which showed no change (SE0013972) or were increased by 7% (SE0013973), which falls within the error of the method used. Consequently, the increase in base paper porosity does not cause the new tobacco products to raise different questions of public health. Both the differences in base paper basis weight and paper mass were minor, and these differences do not cause the new tobacco products to raise different questions of public health. Given the likelihood that the decrease in base paper basis weight and paper mass results

in a decrease in smoke constituent yields, these differences do not cause the new tobacco products to raise different questions of public health. Test data submitted by the applicant show that smoke constituent yields are not adversely affected by the changes in physical parameters. 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 an engineering perspective.

4.3 TOXICOLOGY

Toxicology reviews were completed by Mayo J. Wright on May 15, 2017, and September 13, 2017.

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

- Addition of (b) (4)
- Decrease in (b) (4)
- Change from (b) (4)

The addition of (b) (4) to the new tobacco products may increase smoke yields of carbon monoxide. The applicant provided carbon monoxide yields for the new and corresponding predicate tobacco products. The mean carbon monoxide yields from the new tobacco products in SE0013972 and SE0013973 were slightly increased (8% and 4%, respectively) when compared to the corresponding predicate tobacco products; however, these differences are within the variability of the method. Therefore, the addition of (b) (4) does not cause the new tobacco products to raise different questions of public health. There is some evidence that (b) (4) sources may yield different levels of HPHCs (e.g., crotonaldehyde, phenol, formaldehyde, and acrolein). The applicant submitted HPHC yields in mainstream smoke for acetaldehyde, formaldehyde, acrolein, and benzene. With the exception of formaldehyde, which increased 14% in SE0013972, the yields of all of these HPHCs were reduced in the new tobacco product compared to the corresponding predicate tobacco product. Moreover, although formaldehyde levels increased in SE0013972, this was not considered a significant increase. Consequently, the change in (b) (4) source does not cause the new tobacco products to raise different questions of public health. 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 toxicology perspective.

4.4 SOCIAL SCIENCE

A social science review was completed by Katherine Margolis on May 8, 2017.

The social science review did not identify any differences in characteristics between the new and corresponding predicate tobacco products that could cause the new tobacco products to raise different questions of public health from a social science perspective. 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 social science perspective.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 26, 2018. The FONSI was supported by an environmental assessment prepared by FDA on April 25, 2018.

6. CONCLUSION AND RECOMMENDATION

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

- Addition of (b) (4)
- 15% decrease in (b) (4)
- Change from (b) (4) (SE0013972) (b) (4) (SE0013973) to (b) (4)
- 13% decrease in (b) (4)
- 33% decrease in (b) (4) (SE0013973)
- 33% (SE0013972) or 25% (SE0013793) decrease in (b) (4)
- 16% (SE0013972) or 17% (SE0013793) decrease in (b) (4)
- 2900% increase in base paper porosity
- 14% decrease in base paper basis weight
- 14% decrease in paper mass

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. To address the changes in ingredients, including the change in the source of (b) (4) and the addition of (b) (4), the applicant submitted HPHC data generated from test cigarettes made using the new and corresponding predicate tobacco products and the same commercial tobacco filler. The yield of each HPHC tested was decreased, not significantly different, or slightly increased but within the variability of the method for the new tobacco product compared to the corresponding predicate tobacco product. Given the likelihood that the increase in base paper porosity reduces the tar yields and the amount of tobacco consumed during a single puff, that difference does not cause the new tobacco products to raise different questions of public health. Given the likelihood that the decrease in base paper basis weight and paper mass results in a decrease in smoke constituent yields, these differences do not cause the new tobacco products to raise different questions of public health. Test data submitted by the applicant show that smoke constituent yields are not adversely affected by the changes in physical parameters. 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.

The predicate tobacco products were previously determined to be substantially equivalent by FDA under SE0003299 and SE0003298. 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).

When the new tobacco products in SE0013972 and SE0013973 were initially compared to the grandfathered tobacco products, discrepancies were identified in the applicant's description of the composition of the predicate tobacco products in SE0013972 and SE0013973 (i.e., the products the applicant identified as being previously found substantially equivalent in SE0003299 and SE0003298) and the description of the new tobacco products, which received SE orders, in SE0003299 and SE0003298.[2] FDA sent the applicant an A/I letter asking them to explain the discrepancies in product composition. The applicant clarified that "[t]he ingredient quantities reported for the Predicate Products in SE0013972 and SE0013973 are just reported in different units than the ingredient quantities reported for the [previously found SE] Products in SE0003298 and SE0003299."[3] The applicant provided a mathematical conversion to convert the ingredient quantities to the same unit of measure. This explanation adequately addresses the concern regarding product composition.

Comparison of the new tobacco product in SE0013972 to the grandfathered product in SE0003299 (JOB Tribal King Size) reveals that the new tobacco product has several differences in characteristics from the grandfathered tobacco product. The following differences in characteristics are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0003299:

- Increase in package quantity from 32 to 50 papers
- Decrease in paper length from 109 mm to 77 mm
- 4% increase in (b) (4)
- 80% decrease in (b) (4)
- Addition of (b) (4)
- Removal of (b) (4)

Therefore, these differences do not cause the new tobacco product in SE0013972 to raise different questions of public health. For the same reasons as discussed above, the following differences in characteristics between the new tobacco product in SE0013972 and the grandfathered tobacco product do not cause the new tobacco product to raise different questions of public health:

- Change from (b) (4) to (b) (4)
- 189% increase in (b) (4)
- Removal of (b) (4)
- 6% decrease in (b) (4)
- 33% decrease in (b) (4)
- 1400% increase in base paper porosity
- 8% decrease in base paper basis weight

Therefore, whether comparing the new tobacco product in SE0013972 to the predicate or

[2] *See* February 2, 2018, Memo to File
[3] *See* amendment SE0014503

grandfathered tobacco products, the new tobacco product does not raise different questions of public health.

Comparison of the new tobacco product in SE0013973 to the grandfathered product in SE0003298 (JOB Tribal King Size) reveals that the new tobacco product has several differences in characteristics from the grandfathered tobacco product. The following differences in characteristics are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0003298:

- 4% increase in (b) (4)
- 80% decrease in (b) (4)
- Addition of (b) (4)
- Removal of (b) (4)

Therefore, these differences do not cause the new tobacco product in SE0013973 to raise different questions of public health. For the same reasons as discussed above, the following differences in characteristics between the new tobacco product in SE0013973 and the grandfathered tobacco product do not cause the new tobacco product to raise different questions of public health:

- Change from (b) (4) to (b) (4)
- 189% increase in (b) (4)
- Removal of (b) (4)
- 6% decrease in (b) (4)
- 30% decrease in (b) (4)
- 1400% increase in base paper porosity
- 8% decrease in base paper basis weight

Therefore, whether comparing the new tobacco product in SE0013973 to the predicate or grandfathered tobacco products, the new tobacco product does not raise different questions of public health.

The new tobacco products are 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 products do not raise different questions of public health. I concur with these reviews and recommend that SE order letters be issued.

FDA examined the environmental effects of finding these new tobacco products substantially equivalent and made a finding of no significant impact.

SE order letters should be issued for the new tobacco products in SE0013972 and SE0013973, as identified on the cover page of this review.