Technical Project Lead (TPL) Review: SE0010302, SE0010303, SE0010304

SE0010302: OCB NO.1 Single Wide	
Package Type	Booklet
Package Quantity	50 papers
Length	69 mm
Width	36 mm
Characterizing Flavor	None
SE0010303: OCB Slim	
Package Type	Booklet
Package Quantity	32 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None
SE0010304: OCB Red 1 1/4	
Package Type	Booklet
Package Quantity	75 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 Tobacco
Product Sub-Category	Rolling Paper
Recommendation	
Issue Substantially Equivalent (SE) Orders.	

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S
Date: 2016.12.22 14:22:56 -05'00'

Matthew R. Holman, 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 David Ashley -S
Date: 2016.12.27 09:45:50 -05'00'

David L. Ashley, Ph.D.
RADM, U.S. Public Health Service
Director
Office of Science

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0010302: OCB NO.1 Single Wide	
Product Name	JOB Tribal King Size
Package Type	Booklet
Package Quantity	32 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None
SE0010303: OCB Slim	
Product Name	JOB Tribal King Size
Package Type	Booklet
Package Quantity	32 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None
SE0010304: OCB Red 1 1/4	
Product Name	JOB Gold 1.25
Package Type	Booklet
Package Quantity	24 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None

The predicate tobacco products are roll-your-own (RYO) rolling paper manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 20, 2014, FDA received the three SE Reports subject of this review from Republic Tobacco, LP. FDA issued a Preliminary Finding letter to applicant on April 16, 2014. In response, the applicant submitted an amendment (SE0010454) on April 29, 2014. The applicant also submitted an amendment (SE0010507) on May 23, 2014, in response to FDA's OCE information request dated May 15, 2014. On June 26, 2014, the applicant submitted an amendment (SE0010551) after FDA requested the STNs for the SE Reports that received SE orders supporting predicate eligibility for the predicate tobacco products in SE0010307-SE0010308. FDA issued an Advice/Information Request letter (A/I letter) to applicant on July 30, 2014. In response, the applicant submitted an amendment (SE0010676) on September 16, 2014. On October 14, 2014, the

applicant submitted an amendment (SE0010710) that contained pages 19-21 of their response to A/I letter. FDA issued a Preliminary Finding letter to applicant on May 27, 2015. In response, the applicant submitted an Extension Request on June 3, 2015 (SE0011917). On June 15, 2015, FDA issued an extension denial letter to the applicant. On June 29, 2015, the applicant submitted an amendment in response to the Preliminary Finding letter (SE0012013). On March 29, 2016, the applicant submitted an amendment in response to FDA's information request (SE0013288).

Product Name	SE Report	Amendments
OCB NO.1 Single Wide	SE0010302	SE0010454 SE0010507
OCB Slim	SE0010303	SE0010676 SE0010710
OCB Red 1 1/4	SE0010304	SE0011917 SE0012013 SE0013288

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

Regulatory reviews were completed by Angela Brown on March 27, 2014 and by Sarah Webster on December 22, 2016.

The final reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate tobacco products are grandfathered products (i.e., were commercially marketed as of February 15, 2007). The OCE reviews dated May 30, 2014, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are eligible predicate tobacco products.

OCE also completed a review to determine whether the new tobacco products are 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 July 27 2016, concludes that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

Scientific reviews[1] were completed by the Office of Science (OS) for the following disciplines:

4.1. CHEMISTRY

Chemistry reviews were completed Norman Ohler on July 7, 2014, and December 15, 2014, and by Christina Young on August 26, 2015.

The final chemistry review concludes that the new tobacco products have different characteristics related to product composition 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 did not identify any significant composition differences between the new and corresponding predicate tobacco products. Therefore, the differences in characteristics related to product composition between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

4.2. ENGINEERING

Engineering reviews were completed by James Melchiors on July 1, 2014, December 4, 2014, and August 17, 2015.

The final engineering review concludes that any differences in characteristics relating to product design between the new tobacco products and the corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health. The review identified the following significant differences in design:

- SE0010302: 37% decreased length, 18% decreased width, 56% increased package quantity
- SE0010303: none
- SE0010304: 68% increased package quantity

The smaller dimensions in SE0010302 are expected to reduce the size of the cigarette when tobacco filler is added to the rolling paper, resulting in lower HPHC yields. The increased package quantity in SE0010304 was referred to the social science reviewer[2] for evaluation. Therefore, the differences in

[1] It should be noted that there are errors in the cycle numbers identified in some of the scientific reviews. For all scientific disciplines, the 1st review chronologically was completed prior to issuing the July 30, 2014, A/I letter, the 2nd review chronologically was completed prior to issuing the May 27, 2015, Preliminary Finding letter, and the 3rd review chronologically was completed after issuing the May 27, 2015, Preliminary Finding letter.

[2] See section 4.4 of this review. The social science review concludes that the increase in package quantity does not cause the new tobacco products to raise different questions of public health.

characteristics related to product design between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

4.3. TOXICOLOGY

Toxicology reviews were completed by Zheng Tu on May 12, 2015, and December 28, 2015.

The final toxicology review concludes that any different characteristics relating to toxicology between the new tobacco products and the corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health. The review identified the following significant differences in characteristics:

- SE0010302: none
- SE0010303 (b) (4) increased (b) (4) , (b) (4) increased (b) (4)
- SE0010304: none

Based on calculations by the toxicology reviewer, the (b) (4) quantities in the new tobacco products would not be expected to generate significant HPHC yields. Therefore, the differences in characteristics related to toxicology between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

4.4. SOCIAL SCIENCE

A social science review was completed by Cindy Tworek on July 18, 2014.

The final social science review concludes that any different characteristics relating to consumer perception and use between the new tobacco products and the corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health. The review identified the following significant differences in characteristics:

- SE0010302: decreased package dimensions
- SE0010303: none
- SE0010304: 68% increased package quantity

There is no evidence to suggest that these differences in characteristics affect consumer perception or use. Therefore, the differences in characteristics related to consumer perception or use between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Philip Yeager for Kimberly Benson, Ph.D. on August 29, 2016. The FONSI was supported by an environmental assessment prepared by FDA on August 23, 2016.

6. CONCLUSION AND RECOMMENDATION

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

- SE0010302: 37% decreased length, 18% decreased width, 56% increased package quantity, decreased package dimensions
- SE0010303: (b) (4) increased (b) (4) , (b) (4) increased (b) (4)
- SE0010304: 68% increased package quantity

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The smaller dimension is expected to reduce the size of the cigarette when tobacco filler is added to the rolling paper, resulting in lower HPHC yields. Based on calculations by the toxicology reviewer, the (b) (4) quantities in the new tobacco products would not be expected to generate significant HPHC yields. There is no evidence to suggest that the differences in package dimensions or package quantity affect consumer perception or use. 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 meet statutory requirements because they are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007).

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 SE0010302-SE0010304, as identified on the cover page of this review.