

Technical Project Lead (TPL) Review: SE0015117, SE0015118, SE0015119, and SE0015120

SE0015117: OCB Ultimate 1-1/2	
Package Type	Booklet
Package Quantity	24 papers
Length	77.5 mm
Width	68.5 mm
Characterizing Flavor	None
SE0015118: OCB Ultimate 1-1/4	
Package Type	Booklet
Package Quantity	50 papers
Length	77 mm
Width	44 mm
Characterizing Flavor	None
SE0015119: OCB Ultimate Single Wide	
Package Type	Booklet
Package Quantity	50 papers
Length	69 mm
Width	36 mm
Characterizing Flavor	None
SE0015120: OCB Ultimate 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
Report Type	Regular
Product Category	Roll-Your-Own Tobacco Products
Product Sub-Category	Rolling Paper
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Kenneth Taylor -S
Date: 2019.07.30 15:26:04 -04'00'

Kenneth M. Taylor, Ph.D.
Chemistry Branch Chief
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: 2019.07.30 16:35:20 -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:

SE0015117: OCB Ultimate 1-1/2	
Product Name	JOB TRIBAL KING SIZE
Package Type	Booklet
Package Quantity	32 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None
SE0015118: OCB Ultimate 1-1/4	
Product Name	JOB TRIBAL KING SIZE
Package Type	Booklet
Package Quantity	32 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None
SE0015119: OCB Ultimate Single Wide	
Product Name	JOB TRIBAL KING SIZE
Package Type	Booklet
Package Quantity	32 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None
SE0015120: OCB Ultimate Slim	
Product Name	JOB TRIBAL KING SIZE
Package Type	Booklet
Package Quantity	32 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 13, 2019, FDA received four SE Reports (SE0015117-SE0015120) from Republic Tobacco, LP (Republic) and subsequently issued an acknowledgement letter on March 21, 2019. On March 27, 2019, FDA requested a clarification from Republic regarding the predicate products and on April 3, 2019, FDA received a response from the applicant (SE0015182) clarifying the predicate products for each submission. On May 10, 2019, FDA issued an Advice and Information request letter. The applicant submitted an amendment (SE0015235) on May 17, 2019.

Product Name	SE Report	Amendments
OCB Ultimate 1-1/2	SE0015117	SE0015182 SE0015235
OCB Ultimate 1-1/4	SE0015118	
OCB Ultimate Single Wide	SE0015119	
OCB Ultimate Slim	SE0015120	

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 Anikah Salim on March 20, 2019.

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 April 18, 2019, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered and, therefore, 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 19, 2019, concludes 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

A Chemistry review was completed by Selvin H. Edwards on April 23, 2019.

The 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 review identified the following differences:

- **SE0015117**
 - 967% increase in (b) (4)
 - Addition of (b) (4)
 - 345% increase in (b) (4)
 - 25% decrease in paper leaves per booklet
 - 900% increase in porosity
 - 56% increase in paper width
 - 26% decrease in paper basis weight
 - 29% decrease in paper length

- **SE0015118**
 - 567% increase in (b) (4)
 - Addition of (b) (4) (b) (4)
 - 2150% increase in (b) (4)
 - 56% increase in paper leaves per booklet
 - 900% increase in porosity
 - 26% decrease in paper basis weight
 - 29% decrease in paper length

- **SE0015119**
 - 400% increase in (b) (4)
 - Addition of (b) (4)
 - 1550% increase in (b) (4)
 - 56% increase in paper leaves per booklet
 - 900% increase in porosity
 - 26% decrease in paper basis weight
 - 37% decrease in paper length
 - 18% decrease in paper width

- **SE0015120**
 - 867% increase in (b) (4)
 - Addition of (b) (4)
 - 3100% increase in (b) (4)
 - 56% increase in paper leaves per booklet
 - 900% increase in porosity
 - 26% decrease in paper basis weight

The applicant provided TNCO, acetaldehyde, formaldehyde, acrolein and benzene smoke yields of the new and corresponding predicate tobacco products for all SE Reports by the Canadian Intense smoking regimen. Overall, these HPHC smoke yields of the four new tobacco products were lower compared to the corresponding predicate tobacco products, with the exception of acetaldehyde and formaldehyde in SE0015117 and SE0015120. However, these HPHCs differences were determined to be analytically equivalent. Based on the HPHC results, the differences in ingredient quantities and design attributes are not a concern.

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 Pritesh Darji, on May 1, 2019, and on June 25, 2019.

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:

- **SE0015117**
 - 29% decrease in paper length
 - 56% increase in paper width
 - 20% decrease in paper mass
 - 900% increase in base paper porosity
- **SE0015118**
 - 29% decrease in paper length
 - 48% decrease in paper mass
 - 900% increase in base paper porosity
- **SE0015119**
 - 37% decrease in paper length
 - 18% decrease in paper width
 - 61% decrease in paper mass
 - 900% increase in base paper porosity

- **SE0015120**
 - 26% decrease in paper mass
 - 900% increase in base paper porosity

For SE0015117 and SE0015119, the changes in length, width and mass may lead to an increase in TNCO smoke yields. The change in base paper porosity may lead to a decrease in TNCO, but an increase in benzo- α -pyrene. For SE0015118, the changes in length and mass may lead to an increase in TNCO smoke yields. The change in base paper porosity may lead to a decrease in TNCO, but an increase and benzo- α -pyrene. For SE0015120, the decrease in paper mass and increase in base paper porosity may lead to a decrease in TNCO, but the change in base paper porosity may increase yields of benzo- α -pyrene. As evaluated in the chemistry review, the Canadian Intense smoking regimen HPHC yields in the new tobacco products are either less than or analytically equivalent to those of the corresponding predicate tobacco product. As a result, the design parameter changes do not cause concerns.

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

A toxicology review was completed by Ana S. Depina on April 25, 2019.

The toxicology review concludes that the new tobacco products have different characteristics related to 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 review identified the following differences:

- Addition of (b) (4)
- Increased amounts of (b) (4) and (b) (4)

The differences did not result in analytically important increases in HPHCs when compared to the corresponding predicate product.

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.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on June 25, 2019. The FONSI was supported by an environmental assessment prepared by FDA on June 25, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- **SE0015117**
 - 967% increase in (b) (4)
 - Addition of (b) (4)
 - 345% increase in (b) (4)
 - 25% decrease in paper leaves per booklet
 - 900% increase in porosity
 - 56% increase in paper width
 - 26% decrease in paper basis weight
 - 29% decrease in paper length

- **SE0015118**
 - 567% increase in (b) (4)
 - Addition of (b) (4)
 - 2150% increase in (b) (4)
 - 56% increase in paper leaves per booklet
 - 900% increase in porosity
 - 26% decrease in paper basis weight
 - 29% decrease in paper length

- **SE0015119**
 - 400% increase in (b) (4)
 - Addition of (b) (4)
 - 1550% increase in (b) (4)
 - 56% increase in paper leaves per booklet
 - 900% increase in porosity
 - 26% decrease in paper basis weight
 - 37% decrease in paper length
 - 18% decrease in paper width

- **SE0015120**
 - 867% increase in (b) (4)
 - Addition of (b) (4)
 - 3100% increase in (b) (4)
 - 56% increase in paper leaves per booklet
 - 900% increase in porosity
 - 26% decrease in paper basis weight

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The applicant provided tar, nicotine, carbon monoxide, acetaldehyde, formaldehyde, acrolein and benzene smoke yields for the new and corresponding predicate tobacco products in all SE Reports by the Canadian Intense smoking regimen. Overall, the smoke yields of these HPHCs are either decreased or analytically equivalent in the new tobacco products compared to the corresponding predicate tobacco products. Based on the

HPHC data, the ingredient and design parameter changes in the new tobacco products do not cause concerns. 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 it was determined that they are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets 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 SE0015117, SE0015118, SE0015119, and SE0015120, as identified on the cover page of this review.