

Technical Project Lead (TPL) Review: SE0015132-SE0015136

SE0015132: OCB Organic Hemp 1 1/4 Size	
Package Type	Booklet
Package Quantity	300 sheets
Characterizing Flavor ¹	None
Length	77 mm
Width	44 mm
SE0015133: OCB Virgin 1-1/4	
Package Type	Booklet
Package Quantity	300 sheets
Characterizing Flavor ¹	None
Length	77 mm
Width	44 mm
SE0015134: OCB Premium 1 1/4	
Package Type	Booklet
Package Quantity	300 sheets
Characterizing Flavor ¹	None
Length	77 mm
Width	44 mm
SE0015135: OCB Organic Hemp 1-1/4 Size	
Package Type	Booklet
Package Quantity	300 sheets
Characterizing Flavor ¹	None
Length	77 mm
Width	44 mm
SE0015136: OCB Virgin 1-1/4	
Package Type	Booklet
Package Quantity	300 sheets
Characterizing Flavor ¹	None
Length	77 mm
Width	44 mm

¹ As provided by 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.

Common Attributes of SE Reports	
Applicant	Republic Tobacco, LP
Report Type	Regular Product Quantity Change
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 Colleen K. Rogers -S
Date: 2019.06.11 13:52:07 -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: 2019.06.11 14:04:54 -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:

SE0015132: OCB Organic Hemp 1 1/4 Size	
Product Name	OCB Organic Hemp 1 1/4 Size
Package Type	Booklet
Package Quantity	50 sheets
Characterizing Flavor ¹	None
Length	77 mm
Width	44 mm
SE0015133: OCB Virgin 1-1/4	
Product Name	OCB Virgin 1-1/4
Package Type	Booklet
Package Quantity	50 sheets
Characterizing Flavor ¹	None
Length	77 mm
Width	44 mm
SE0015134: OCB Premium 1 1/4	
Product Name	OCB XPERT 1 1/4
Package Type	Booklet
Package Quantity	32 sheets
Characterizing Flavor ¹	None
Length	77 mm
Width	44 mm
SE0015135: OCB Organic Hemp 1-1/4 Size	
Product Name	OCB Organic Hemp 1-1/4 Size
Package Type	Booklet
Package Quantity	50 sheets
Characterizing Flavor ¹	None
Length	77 mm
Width	44 mm

SE0015136: OCB Virgin 1-1/4	
Product Name	Job Pristine 1-1/4
Package Type	Booklet
Package Quantity	50 sheets
Characterizing Flavor ¹	None
Length	77 mm
Width	44 mm

The predicate tobacco products are roll-your-own rolling papers manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 21, 2019, FDA received five Product Quantity Change SE Reports (SE0015132-SE0015136) from Republic Tobacco, LP. FDA issued an Acknowledgement letter to the applicant on March 28, 2019. On April 12, 2019, FDA held a teleconference with the applicant, requesting clarification of a question regarding the packaging arrangement of the new tobacco products. On April 17, 2019, FDA received an amendment (SE0015200) containing the applicant's response to the clarification question.

Product Name	SE Report	Amendments
OCB Organic Hemp 1 1/4 Size	SE0015132	SE0015200
OCB Virgin 1-1/4	SE0015133	
OCB Premium 1 1/4	SE0015134	
OCB Organic Hemp 1-1/4 Size	SE0015135	
OCB Virgin 1-1/4	SE0015136	

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 Nicholas Hasbrouck on March 28, 2019.

The reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco products in SE0015132-SE0015136 were previously determined to be substantially equivalent by FDA as shown in the table below. Therefore, the predicate tobacco products are eligible predicate tobacco products.

SE Report	Predicate Tobacco Product	Predicate Tobacco Product Found SE Under:	SE Order Date
SE0015132	OCB Organic Hemp 1 1/4 Size	SE0003299	October 9, 2013
SE0015133	OCB Virgin 1-1/4	SE0013972 ²	April 27, 2018
SE0015134	OCB Premium 1 1/4	SE0014036 ³	April 5, 2018
SE0015135	OCB Organic Hemp 1-1/4 Size	SE0012933 ²	June 30, 2017
SE0015136	OCB Virgin 1-1/4	SE0014417 ⁴	June 25, 2018

The Office of Compliance and Enforcement (OCE) completed a review 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 review dated April 26, 2019, concludes that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

Scientific review was not initiated by the Office of Science (OS) because the product characteristics of the new and corresponding predicate tobacco products are identical except for a change in product quantity. OS prepared a memorandum⁵ summarizing its current thinking on product quantity changes. With respect to product quantity increases, the currently available scientific evidence examines the effects of product quantity in other consumer products on consumer behavior and perception but is not specific to tobacco products generally or the specific category of tobacco product under social science review. This evidence suggests that changes in product quantity of consumer products may influence consumer behavior but was not specific enough for OS to determine if such changes always lead to changes in behavior, and, if not, under what condition it would; what threshold (if any) would trigger a change in consumer behavior; what tobacco products would be affected by a quantity change and which would not, and how findings about consumer behavior and use of other consumer products may translate to tobacco use intention and behavior. 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 Shannon Hanna on April 9, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on May 15, 2019. The FONSI was supported by an environmental assessment prepared by FDA on May 15, 2019.

² The predicate tobacco products in SE0013972 and SE0012933 were previously determined to be substantially equivalent by FDA under SE0003299.

³ The predicate tobacco product in SE0014036 was previously determined to be substantially equivalent by FDA under SE0003298.

⁴ The predicate tobacco product in SE0014417 was previously determined to be substantially equivalent by FDA under SE0012926.

⁵ See memorandum on product quantity changes, dated December 7, 2017.

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate tobacco products are identical except for the following changes in product quantity:

- SE0015132-SE0015133 and SE0015135-SE0015136: 500% increase (from 50 to 300 rolling papers)
- SE0015134: 838% increase (from 32 to 300 rolling papers)

The OS memorandum⁵ concludes that based on OS' experience and the currently available evidence, the difference in product quantity does not cause the new tobacco products to raise different questions of public health. I concur with this conclusion.

The predicate tobacco products in SE0015132-SE0015136 meet statutory requirements because they were previously determined to be substantially equivalent by FDA under SE0003299, SE0013972, SE0014036, SE0012933, and SE0014417, respectively.

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 other than exclusively in test markets as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act).

The predicate tobacco product in SE0015132 was previously determined to be substantially equivalent by FDA under SE0003299. Comparison of the new tobacco product to the grandfathered product (JOB Tribal King Size) reveals that the new tobacco product has the following differences in characteristics from JOB Tribal King Size, the grandfathered tobacco product:

- 838% increase in product quantity (from 32 to 300 rolling papers)
- 80% decrease in (b)(4)
- 50% decrease in base paper porosity (from 2 to 1 CORESTA Units)
- 29% decrease in paper length (from 109 to 77 mm)
- 8% increase in base paper basis weight (from 13 to 14 g/m²)

As discussed in section 4 above, the difference in product quantity between the new tobacco product in SE0015132 and the grandfathered tobacco product does not cause the new tobacco product to raise different questions of public health. Additionally, the differences in characteristics listed above, other than the difference in product quantity, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0003299. Therefore, these differences do not cause the new tobacco product in SE0015132 to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0015132 to the predicate or grandfathered tobacco product, the new tobacco product does not raise different questions of public health.

The predicate tobacco product in SE0015133 was previously determined to be substantially equivalent by FDA under SE0013972, and the predicate tobacco product in SE0013972 was previously determined to be substantially equivalent by FDA under SE0003299. Therefore, the grandfathered product for this comparison is the predicate tobacco product in SE0003299.

Comparison of the new tobacco product to the grandfathered product (JOB Tribal King Size) reveals that the new tobacco product has the following differences in characteristics from JOB Tribal King Size, the grandfathered tobacco product:

- 838% increase in product quantity (from 32 to 300 rolling papers)
- 80% decrease in (b)(4)
- 1400% increase in base paper porosity (from 2 to 30 CORESTA Units)
- 29% decrease in paper length (from 109 to 77 mm)
- 8% decrease in base paper basis weight (from 13 to 12 g/m²)
- 189% increase in (b)(4)
- Removal of (b)(4)
- 4% increase in (b)(4)
- Change from (b)(4) derived from (b)(4) to (b)(4) derived from (b)(4)
- Addition of (b) (4)
- 33% decrease in (b)(4) color (b)(4)
- 6% decrease in (b)(4)
- Removal of (b)(4)

As discussed in section 4 above, the difference in product quantity between the new tobacco product in SE0015133 and the grandfathered tobacco product does not cause the new tobacco product to raise different questions of public health. Additionally, the differences in characteristics listed above, other than the difference in product quantity, are the same differences in characteristics identified for the new tobacco product in SE0013972 and the grandfathered tobacco product. Thus, these differences do not cause the new tobacco product in SE0015133 to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0015133 to the predicate or grandfathered tobacco product, the new tobacco product does not raise different questions of public health.

The predicate tobacco product in SE0015134 was previously determined to be substantially equivalent by FDA under SE0014036, and the predicate tobacco product in SE0014036 was previously determined to be substantially equivalent by FDA under SE0003298. Therefore, the grandfathered product for this comparison is the predicate tobacco product in SE0003298. Comparison of the new tobacco product to the grandfathered product (JOB Tribal King Size) reveals that the new tobacco product has the following differences in characteristics from JOB Tribal King Size, the grandfathered tobacco product:

- 838% increase in product quantity (from 32 to 300 rolling papers)
- 70% decrease in (b)(4)
- 3% decrease in (b)(4)
- 1980% increase in (b)(4)
- 389% increase in (b)(4)
- 2400% increase in base paper porosity (from 2 to 50 CORESTA Units)
- 29% decrease in paper length (from 109 to 77 mm)

As discussed in section 4 above, the difference in product quantity between the new tobacco product in SE0015134 and the grandfathered tobacco product does not cause the new tobacco product to raise different questions of public health. Additionally, the differences in (b)(4) are the same differences in characteristics

identified for the new tobacco product in SE0014036 and the grandfathered tobacco product. An increase in base paper porosity is expected to decrease the coal temperature of the cigarette and reduce the amount of tar, nicotine, and carbon monoxide (TNCO) produced. The decrease in paper length does not cause the new tobacco product to raise different questions of public health because it reduces the amount of tobacco that can be rolled and the amount of paper available to be burned. Thus, these differences do not cause the new tobacco product in SE0015134 to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0015134 to the predicate or grandfathered tobacco product, the new tobacco product does not raise different questions of public health.

The predicate tobacco product in SE0015135 was previously determined to be substantially equivalent by FDA under SE0012933, and the predicate tobacco product in SE0012933 was previously determined to be substantially equivalent by FDA under SE0003299. Therefore, the grandfathered product for this comparison is the predicate tobacco product in SE0003299. Comparison of the new tobacco product to the grandfathered product (JOB Tribal King Size) in SE003299 reveals that the new tobacco product has the following differences in characteristics from JOB Tribal King Size, the grandfathered tobacco product:

- 838% increase in product quantity (from 32 to 300 rolling papers)
- 29% decrease in paper length (from 109 to 77 mm)
- 8% increase in base paper basis weight (from 13 to 14 g/m²)
- 96% decrease in (b)(4)
- 50% decrease in base paper porosity (from 2 to 1 CORESTA Units)
- Removal of (b)(4)
- Addition of (b)(4)

As discussed in section 4 above, the difference in product quantity between the new tobacco product in SE0015135 and the grandfathered tobacco product does not cause the new tobacco product to raise different questions of public health. The decrease in paper length does not cause the new tobacco product to raise different questions of public health because it reduces the amount of tobacco that can be rolled and the amount of paper available to be burned. The increase in base paper basis weight and decrease in (b)(4) are expected to lead to a decrease in base paper porosity, as observed. The applicant previously submitted studies examining the impact of paper porosity on tar yields. Based on those studies, it is not expected that the small decrease in paper porosity would affect tar or HPHC yields. Therefore, the increase in base paper basis weight and decrease in (b)(4) does not cause the new tobacco product to raise different questions of public health. The removal of (b)(4) and addition of (b)(4) does not cause the new tobacco product to raise different questions of public health in this particular case because, although the (b)(4) are different, the overall level of (b)(4) in the new tobacco product remains similar to the grandfathered tobacco product and is not expected to affect the levels of HPHCs. Thus, these differences do not cause the new tobacco product in SE0015135 to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0015135 to the predicate or grandfathered tobacco product, the new tobacco product does not raise different questions of public health.

The predicate tobacco product in SE0015136 was previously determined to be substantially equivalent by FDA under SE0014417, and the predicate tobacco product in SE0014417 was previously determined to be substantially equivalent by FDA under SE0012926. Therefore, the

grandfathered product for this comparison is the predicate tobacco product in SE0012926. Comparison of the new tobacco product to the grandfathered product (JOB Tribal King Size) in SE0012926 reveals that the new tobacco product has the following differences in characteristics from JOB Tribal King Size, the grandfathered tobacco product:

- 838% increase in product quantity (from 32 to 300 rolling papers)
- Addition of (b)(4)
- Removal of (b)(4)
- 36% decrease in (b)(4)
- 29% decrease in paper length (from 109 to 77 mm)
- 650% increase in base paper porosity (from 4 to 30 CORESTA Units)
- 11% decrease in base paper basis weight (from 13.5 to 12 g/m²)

As discussed in section 4 above, the difference in product quantity between the new tobacco product in SE0015136 and the grandfathered tobacco product does 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 and paper length, are the same differences in characteristics identified for the new tobacco product in SE0014417 and the grandfathered tobacco product. The decrease in paper length does not cause the new tobacco product to raise different questions of public health because it reduces the amount of tobacco that can be rolled and the amount of paper available to be burned. Thus, these differences do not cause the new tobacco product in SE0015136 to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0015136 to the predicate or grandfathered tobacco product, 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.

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 SE0015132-SE0015136, as identified on the cover page of this review.