

**Technical Project Lead (TPL) Review:
SE0014410 - SE0014417**

SE0014410: JOB PRISTINE 1-1/4	
Package Type	Booklet
Package Quantity	50 sheets
Length	77 mm
Width	44 mm
Characterizing Flavor	None
Additional Properties	Utilizes (b) (4)
SE0014411: JOB PRISTINE SINGLE WIDE	
Package Type	Booklet
Package Quantity	50 sheets
Length	69 mm
Width	36 mm
Characterizing Flavor	None
Additional Properties	Utilizes (b) (4)
SE0014412: JOB PRISTINE SINGLE WIDE	
Package Type	Booklet
Package Quantity	50 sheets
Length	69 mm
Width	36 mm
Characterizing Flavor	None
Additional Properties	Utilizes (b) (4)
SE0014413: JOB PRISTINE SLIM	
Package Type	Booklet
Package Quantity	32 sheets
Length	109 mm
Width	44 mm
Characterizing Flavor	None
Additional Properties	Utilizes (b) (4)
SE0014414: JOB PRISTINE 1-1/2	
Package Type	Booklet
Package Quantity	24 sheets
Length	77.5 mm
Width	68.5 mm
Characterizing Flavor	None
Additional Properties	Utilizes (b) (4)

SE0014415: JOB PRISTINE 1-1/2	
Package Type	Booklet
Package Quantity	24 sheets
Length	77.5 mm
Width	68.5 mm
Characterizing Flavor	None
Additional Properties	Utilizes (b) (4)
SE0014416: JOB PRISTINE SLIM	
Package Type	Booklet
Package Quantity	32 sheets
Length	109 mm
Width	44 mm
Characterizing Flavor	None
Additional Properties	Utilizes (b) (4)
SE0014417: JOB PRISTINE 1-1/4	
Package Type	Booklet
Package Quantity	50 sheets
Length	77 mm
Width	44 mm
Characterizing Flavor	None
Additional Properties	Utilizes (b) (4)
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) orders.	

Technical Project Lead (TPL):

Matthew J. Walters -S
2018.06.25 08:06:04 -04'00'

Matthew Walters, Ph.D., MPH
CDR, US Public Health Service
Deputy 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 Glen D. Jones -S
Date: 2018.06.25 14:53:10 -04'00'

For 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:

SE0014410: JOB PRISTINE 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
Additional Property	GF product
SE0014411: JOB PRISTINE SINGLE WIDE	
Product Name	Job Tribal King Size
Package Type	Booklet
Package Quantity	32 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None
Additional Property	GF product
SE0014412: JOB PRISTINE SINGLE WIDE	
Product Name	Job Tribal King Size
Package Type	Booklet
Package Quantity	32 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None
Additional Property	Product subject of SE0012926
SE0014413: JOB PRISTINE SLIM	
Product Name	Job Tribal King Size
Package Type	Booklet
Package Quantity	32 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None
Additional Property	Product subject of SE0012926

SE0014414: JOB PRISTINE 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
Additional Property	GF product
SE0014415: JOB PRISTINE 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
Additional Property	Product subject of SE0012926
SE0014416: JOB PRISTINE SLIM	
Product Name	Job Tribal King Size
Package Type	Booklet
Package Quantity	32 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None
Additional Property	Product subject of SE0012926
SE0014417: JOB PRISTINE 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
Additional Property	Product subject of SE0012926

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On November 22, 2017, FDA received eight SE Reports from Republic Tobacco, LP. FDA issued Acknowledgement letters to the applicant on November 29, 2017. FDA issued an advice and

information letter on February 16, 2018. In response, the applicant submitted an amendment (SE0014595), which FDA received on March 27, 2018.

Product Name	SE Report	Amendments
JOB PRISTINE 1-1/4	SE0014410	SE0014595
JOB PRISTINE SINGLE WIDE	SE0014411	
JOB PRISTINE SINGLE WIDE	SE0014412	
JOB PRISTINE SLIM	SE0014413	
JOB PRISTINE 1-1/2	SE0014414	
JOB PRISTINE 1-1/2	SE0014415	
JOB PRISTINE SLIM	SE0014416	
JOB PRISTINE 1-1/4	SE0014417	

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 November 29, 2017.

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 in SE0014410, SE0014411, and SE0014414 are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews dated December 28, 2017, 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.¹

The predicate tobacco product in SE0014412 - SE0014413 and SE0014415 - SE0014417 was determined to be substantially equivalent by FDA under SE0012926. Therefore, this product is an eligible predicate tobacco product.

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) (see section 910(a)(2)(A)(i)(II) of the

¹ Addendum reviews were completed on June 14, 2018 for SE0014410, June 15, 2018 for SE0014411, and June 18, 2018 for SE0014414 to clarify that the characterizing flavor of the predicate tobacco product is "none." The addendum reviews do not change the conclusion of the initial grandfathered determination dated December 28, 2017.

FD&C Act). The OCE review dated May 30, 2018, 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

Chemistry reviews were completed by Melis Coraggio on January 26, 2018, and May 10, 2018.

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 review identified the following differences:

- Increased amount of (b) (4) mg/leaf (1%) and (b) (4) mg/leaf (4%) for SE0014414 and SE0014415, respectively)
- Decrease in the amount of (b) (4) used for SE0014410-SE0014413 and SE0014416-SE0014417
- 7% and 13% increase in benzene yield under CI smoking regimen (SE0014413 and SE0014416, respectively)
- Decreased amount of (b) (4) (25 – 50% in all the new products)
- Decreased amount of (b) (4) (37 – 98% in all the new products)
- Decreased amount of (b) (4) (2% - 100% for SE0014412, SE0014413, and SE0014415 -SE0014417 only)
- Increased amount of (b) (4) (81% - 3100% in SE0014410, SE0014411, SE0014414, and SE0014416)

The new products consist of different quantities of (b) (4) as compared to the corresponding predicate products, however to demonstrate that these ingredients do not raise different questions in public health the applicant provided mainstream smoke (MSS) HPHC data for the new and corresponding predicate products. The new and corresponding predicate products were measured with five replicates in the measurements for tar, carbon monoxide, acetaldehyde, formaldehyde, acrolein, and benzene. The mean level of tar is lower for all new products than in the corresponding predicate products except for SE0014413, where the measured tar is 8% higher in the new product. However, this increase in 8% for SE0014413 is within the analytical variability of these measurements and does not cause the new product to raise different questions of public health. The level of carbon monoxide is lower in all new products except for SE0014413 and SE0014416 that are higher by 8% and 4% respectively. The remaining measured HPHCs (tar, CO, acetaldehyde, formaldehyde, acrolein, benzene) for SE0014410 – SE0014412 and SE0014417 all are less in the new products as compared to the corresponding predicate product. The new products of SE0014413 and SE0014416 have higher yields of benzene in mainstream smoke levels (7% and 13%, respectively) as compared to the corresponding predicate products. The applicant addressed this issue by providing five additional

measurements of benzene under CI smoking regimens in the new and predicate products. The statistical calculations of all benzene data indicate that benzene yields between the new and corresponding predicate products are not statistically different. 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 January 26, 2018 and by Robert Meyer, on May 9, 2018.²

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:

- Decreased surface area³ (29% and 48% for SE0014410- SE0014412 and SE0014417, respectively)
- Increased surface area³ (10% for SE0014414 and SE0014415)
- Increased base paper porosity (26 CU for all new products)
- Decreased base paper basis weight (11% for all new products)

For SE0014410, SE0014411, SE0014412, SE0014417, the rolling paper surface area is decreased due to a reduction in either the width or the length dimension. A decrease in surface area results in less paper available to be burned, and, consequently, the HPHC yields decreased in the new products compared to the corresponding predicate products. For SE0014414 and SE0014415, the new product surface area increased due to a 56% increase in the overall width, and only a 29% decrease in overall length. The increased surface area increases the availability of paper to be burned, but the HPHC yields decreased in the new products compared to the corresponding predicate products. All new products have the target paper porosity of 30 CU, while the predicate products have the base paper porosity of 4 CU, which is a 650% increase in the new products. The increase in paper porosity is expected to lower HPHC yields, which has been demonstrated. The target specification values for the new products paper mass and base paper basis weight are decreased by 4 – 54% and 11%, respectively. A decrease in paper mass or base paper basis weight translates to less paper available to be combusted, resulting in unchanged or decreased HPHC yields as demonstrated. 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.

² A memo dated May 21, 2018 was completed to correct a typographical error in the STN numbers of the SE Reports. This memo does not alter the conclusions of the engineering review dated May 9, 2018.

³ Length x width

4.3. TOXICOLOGY

Toxicology reviews were completed by Ana Depina, on January 24, 2018 (for all SE Reports), and on May 15, 2018 (SE0014413, SE0014415, and SE0014416 only).

The final 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) (SE0014410, SE0014411, SE0014412, and SE0014414)
- Increased amount of (b) (4) (81% - 3100% in SE0014410, SE0014411, SE0014414, and SE0014416)
- Decreases or insignificant increases in HPHC yields

For the same reasons as explained in the Chemistry section of this TPL review, the HPHC data demonstrate that HPHC yields from the new and corresponding predicate tobacco products are comparable. 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 22, 2018. The FONSI was supported by an environmental assessment prepared by FDA on June 22, 2018.

6. CONCLUSION AND RECOMMENDATION

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

- Increased amount of (b) (4) mg/leaf (1%) and (b) (4) mg/leaf (4%) for SE0014414 and SE0014415, respectively)
- Decrease in the amount of (b) (4) used for SE0014410-SE0014413 and SE0014416-SE0014417
- 7% and 13% increase in benzene yield under CI smoking regimen (SE0014413 and SE0014416, respectively)
- Decreased amount of (b) (4) (25 – 50% in all the new products)
- Decreased amount of (b) (4) (37 – 98% in all the new products)
- Decreased amount of (b) (4) (2% - 100% for SE0014412, SE0014413, and SE0014415 -SE0014417 only)
- Increased amount of (b) (4) (81% - 3100% in SE0014410, SE0014411, SE0014414, and SE0014416)
- Decreased surface area (29% and 48% for SE0014410- SE0014412 and SE0014417, respectively)
- Increased surface area1 (10% for SE0014414 and SE0014415)

- Increased base paper porosity (26 CU for all new products)
- Decreased base paper basis weight (11% for all new products)
- Addition of (b) (4) (SE0014410, SE0014411, SE0014412, and SE0014414)

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 has indicated that there are differences in quantities of (b) (4) as compared to the corresponding predicate products. In addition, there are minimal differences in the surface area, base paper porosity, and base paper basis weight between the new and corresponding predicate tobacco products. The applicant provided HPHC data to demonstrate that these changes in ingredients and product design features do not cause the new products to raise different questions of public health, as the provided data demonstrate that there are decrease in the HPHC yields or minimal increases that are within the expected variability of the analytical measurements. 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 in SE0014410, SE0014411, and SE0014414 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). Additionally, the predicate tobacco products in SE0014412 – SE0014413 and SE0014415 – SE0014417 were previously determined to be substantially equivalent by FDA under SE0012926.

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 products in SE0014412 – SE0014413 and SE0014415 – SE0014417 were previously determined to be substantially equivalent by FDA under SE0012926. Comparison of the new tobacco products to the grandfathered product (JOB Tribal King Size) in SE0012926 reveals that the new tobacco products have the following differences in characteristics from JOB Tribal King Size, the grandfathered tobacco product:

- Decrease in (b) (4)
- Decrease in (b) (4)
- Minimal changes in (b) (4)
- Change in package quantity
- Change in base paper porosity
- Change in base paper weight

The differences in characteristics listed above, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0012926. Therefore, these differences do not cause the new tobacco products in SE0014412 – SE0014413 and SE0014415 – SE0014417 to raise different questions of public health. Additionally, the differences between the new tobacco products in SE0014412 – SE0014413 and SE0014415 – SE0014417 and the grandfathered tobacco

products do not cause the new tobacco products to raise different questions of public health. Therefore, whether comparing the new tobacco products in SE0014412 – SE0014413 and SE0014415 – SE0014417 to the predicate or grandfathered tobacco products, the new tobacco products do 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 SE0014410 – SE0014417, as identified on the cover page of this review.