FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review:

SE0014228

SE0014228: JOB 1.25 SLIM GOLD	
Package Type	Booklet
Package Quantity	32 sheets
Length	109 mm
Width	44 mm
Characterizing Flavor	None
Additional Properties	Slim Gold
Common Attributes of SE Reports	
Applicant	Republic Tobacco, LP
Report Type	Regular
Product Category	Roll-Your-Own
Product Sub-Category	Rolling Paper
Recommendation	
Issue a Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Todd L. Cecil -A
Digitally signed by Todd L. Cecil -A
Date: 2018.03.16 15:33:34 -04'00'

Todd Cecil, Ph.D.
Associate 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: 2018.03.16 16:00:44 -04'00'

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0014228: JOB 1.25 SLIM GOLD	
Product Name	ORGANIC HEMP KING SIZE SLIM
Package Type	Booklet
Package Quantity	32 papers
Length	109 mm
Width	44 mm
Characterizing Flavor	None
Additional Properties	Organic Hemp

The predicate tobacco product is a roll-your-own (RYO) rolling paper manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The FDA received this SE Report on August 3, 2017, and sent an Acknowledgement letter on August 14, 2017. FDA issued an Advice/Information Request (A/I) letter to the applicant on October 23, 2017. In response, the applicant submitted amendment SE0014437, which FDA received on December 19, 2017.

Product Name	SE Report	Amendments
JOB 1.25 Slim Gold	SE0014228	SE0014437

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for this SE Report.

2. REGULATORY REVIEW

An acceptance review was completed by Ryan Nguy on August 14, 2017.

The final review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco product in SE0014228 was determined to be substantially equivalent by FDA under SE0003298. Therefore, this product is an eligible predicate tobacco product.

OCE also completed a review to determine whether the new tobacco product is 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 March 5, 2018 concludes that the new tobacco product is 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 Jianping Gong on October 05, 2017, and February 08, 2018.

The final chemistry review concludes that the new tobacco product has different characteristics related to product composition compared to the predicate tobacco product but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following issues related to product composition:

- The new product contains (b)(4) while the predicate products contain (b)(4) derived from (b).
- (b)(4) is higher by (b) (4) ((b) (4) mg/product) in the new product compared to the predicate product ((b) (4) mg/product).
- (b)(4) mg/product) and (b)(4) mg/product) are present in the new product, but not in the predicate product.

The new product contains (b) (4) mg/product of (b)(4), which is (b) (4) higher compared to the predicate product ((b) (4) mg/product). The applicant addressed the deficiency by providing measurements of benzo[a]pyrene in the test cigarettes for the new and predicate products. The B[a]P yields in the test cigarettes for the new and predicate products under CI smoking regimens resulted in minimal changes. The use of (b)(4) and (b)(4) and the change in fiber source (b) (4)) in the new product may lead to increases in carbonyls (i.e. acetaldehyde and formaldehyde), volatile organic compounds (VOC) (i.e. benzene), and carbon monoxide. The applicant provided smoke results test cigarettes prepared with the new and predicate tobacco products, and the results demonstrated no statistically significant increases in the carbonyls, VOCs, or carbon monoxide. Therefore, the differences in characteristics related to product composition between the new and predicate products do not cause the new product to raise different questions of public health.

4.2. ENGINEERING

Engineering reviews were completed by Rashele Moore on September 28, 2017, and January 24, 2018.

The final engineering review concludes that the new tobacco product has different characteristics related to product design compared to the corresponding predicate tobacco

product but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following issues related to product design:

- Increase in cigarette paper mass by 17%
- Increase in roll-your-own base paper basis weight by 18%
- Increase in roll-your-own base paper porosity by 800%

All of these differences may increase HPHC yields of the new product compared to the predicate product. However, HPHC data submitted by the applicant do not reveal any significant increases in HPHC yields of the new product. Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco product to raise different questions of public health related to product design.

4.3. TOXICOLOGY

Toxicology reviews were completed by Yanling Chen on October 05, 2017, and February 06, 2018.

The final toxicology review concludes that the new tobacco product has different characteristics related to toxicology compared to the predicate tobacco product but the differences do not cause the new tobacco product to raise different questions of public health. Namely, HPHC data submitted by the applicant do not reveal any significant increases in HPHC yields of the new product. Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco product to raise different questions of public health related to toxicology.

4.4. SOCIAL SCIENCE

Social science reviews were completed by Elizabeth Sherman on October 06, 2017.

The final social science review concludes that there are no differences in characteristics which may affect consumer perception and use for the new and predicate tobacco product.

The review also evaluated the health information summary and determined that it did not violate section 911(b)(2)(A)(i)(II) of the FD&C Act. Therefore, the final review did not identify a deficiency related to the health information summary.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on March 13, 2018. The FONSI was supported by an environmental assessment prepared by FDA on March 13, 2018.

6. CONCLUSION AND RECOMMENDATION

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

- Increase in cigarette paper mass by 17%
- Increase in roll-your-own base paper basis weight by 18%
- Increase in roll-your-own base paper porosity by 800%
- The new product contains [redacted] while the predicate products contain [redacted] derived from [redacted].
- [redacted] is higher by [redacted] mg/product) in the new product compared to the predicate product ([redacted] mg/product).
- [redacted] mg/product) and [redacted] mg/product) are present in the new product, but not in the predicate product.

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The stated increase in paper mass is proportional to the increase in the cigarette paper base paper basis weight because the paper is the primary constituent in this tobacco product. The increase in the paper mass (and cigarette paper base paper basis weight) may result in increases in the typical pyrolysis products of the paper, which are primarily carbon monoxide and tar. The applicant provided smoke chemistry results of test cigarettes prepared from the new and predicate tobacco products. These results showed a decrease in tar and carbon monoxide values for the test cigarettes prepared with the new tobacco product when compared to the predicate tobacco product. The change in the cigarette paper base paper porosity may result in changes in TNCO and particulate-borne HPHCs, such as B[a]P. The applicant provided smoke chemistry results of test cigarettes prepared from the new and predicate tobacco products, which showed lower levels for TNCO and B[a]P in the new tobacco product than in the predicate tobacco product. The change in source of fiber in the paper will change the physical parameters in the cigarette paper and may also result in changes in carbon monograph and carbonyls (formaldehyde and acetaldehyde). The smoke chemistry results of test cigarettes prepared from the new and predicate tobacco products, showed no statistically significant increase in TNCOs, acetaldehyde, and formaldehyde. The larger amount of calcium carbonate filler used in the new tobacco product may result in increases in TNCO and B[a]P, due largely to the change in porosity. The applicant provided smoke chemistry results of test cigarettes prepared from the new and predicate tobacco products, which showed lower levels for TNCO and B[a]P in the new tobacco product than in the predicate tobacco product. The addition of [redacted] in the adhesive and [redacted] as a release coating on the cigarette paper may result in higher measured values of acetaldehyde, formaldehyde, and benzene in smoke of the new tobacco product. The applicant provided test results from the new and predicate tobacco products, which showed lower levels for acetaldehyde, formaldehyde, and benzene in the new tobacco product than in the predicate tobacco product. Therefore, the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health.

The predicate tobacco product was determined to be substantially equivalent by FDA under SE0003298. A comparison of the new tobacco product to the grandfathered product presented in SE0003298 indicates substantive changes in [redacted] content, but no substantive changes to other ingredients or product design characteristics. The higher content of [redacted] in the new tobacco product may result in increases in TNCO and B[a]P. The applicant did not provide

TNCO or B[a]P measurements for the grandfathered tobacco product in SE00032989 or SE0014228. However, the content of (b)(4) in the grandfathered product is higher than the amount of the predicate product for SE0014228. However, the differences in (b)(4) between the new and grandfather products would be expected to be smaller than those between the new and predicate products for which data has been provided. Therefore, differences in characteristics between the new and grandfathered tobacco product do not cause the new tobacco product to raise different questions of public health.

The new tobacco product is currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude that the differences between the new and predicate tobacco products are such that the new tobacco product does not raise different questions of public health. I concur with these reviews and recommend that an SE order letter be issued.

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

An SE order letter should be issued for the new tobacco product in SE0014228, as identified on the cover page of this review.