FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0012826

SE0012826: Rolling Standard	
Package Type	Booklet
Package Quantity	125 papers
Length	70 mm
Width	39 mm
Characterizing Flavor[1]	None
SE Report Attributes	
Applicant	Republic Tobacco, LP
Report Type	Product Quantity Change Regular
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Rolling Paper
Recommendation	
Issue a Substantially Equivalent (SE) order.	

[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.

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2018.05.15 21:35:58 -04'00'

Colleen K. Rogers, Ph.D.
Director
Division of Product Science
Office of 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: 2018.05.16 08:18:59 -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:

SE0012826: Rolling Standard	
Product Name	TOP CIG PAPER 24's[2]
Package Type	Booklet
Package Quantity	100 papers
Length	70 mm
Width	39 mm
Characterizing Flavor[3]	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On January 29, 2016, FDA received the SE Report from Republic Tobacco, LP. On February 25, 2016, a teleconference was held with the applicant to clarify the units of measurement for the length and width of the new and predicate tobacco products. In response, FDA received an amendment (SE0012986) on February 29, 2016, containing the requested information. FDA subsequently issued an Acknowledgement letter on March 1, 2016. On March 18, 2016, FDA received an amendment (SE0013017) containing a response to the Office of Compliance and Enforcement's (OCE) inquiry on further clarification of the predicate tobacco product name. In the original application, the applicant referenced the predicate tobacco product name as Top Standard. However, the application also notes that on February 15, 2007, the name of the product was TOP CIG PAPER 24's. In amendment SE0013017, the applicant clarified that as of February 15, 2007, the name for the predicate tobacco product (Top Standard) was Top CIG PAPER 24's. Additionally, the applicant noted "The predicate product characteristics, design features and ingredients remain otherwise unchanged from their February 15, 2007, format as presented in the 905(j) reports." Given the name change, on March 22, 2016, FDA requested an amended certification statement be submitted to FDA.[4] On March 25, 2016, FDA received an amendment (SE0013035) with the amended certification statement referencing the predicate tobacco product "TOP CIG PAPER 24's." On January 31, 2018, FDA issued a Preliminary Finding letter. On February 16, 2018, FDA received an amendment (SE0014538) with the applicant's responses to the Preliminary Finding letter. On

[2] In the original application, the applicant referenced the predicate tobacco product as Top Standard. In amendment SE0013017, the applicant clarified that the predicate tobacco product name as of February 15, 2007, was TOP CIG PAPER 24's. The SE Report was amended to reflect the predicate tobacco product as TOP CIG PAPER 24's.

[3] 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.

[4] In an opinion issued on August 16, 2016, the District Court for the District of Columbia found that "a modification to an existing product's label does not result in a 'new tobacco product.'" *Philip Morris USA Inc. v. United States Food and Drug Administration*, 202 F. Supp. 3d 31, 36 (D.D.C. 2016).

March 28, 2018, FDA held a teleconference with the applicant in which FDA requested a clarification to the applicant's response to the Preliminary Finding letter. In response, the applicant submitted an amendment (SE0014600), which was received on March 29, 2018.

Product Name	SE Report	Amendments
Rolling Standard	SE0012826	SE0012986 SE0013017 SE0013035 SE0014538 SE0014600

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

A regulatory review was completed by Sarah Webster on February 26, 2016. The review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the predicate tobacco product is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated March 30, 2016, concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and, therefore, is an eligible predicate tobacco product.[5]

OCE also completed reviews to determine whether the new tobacco product is 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 reviews dated April 11, 2016; July 27, 2016; and April 24, 2018, conclude that the new tobacco product is in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

A scientific review was completed by the Office of Science (OS) for the following discipline:

4.1. SOCIAL SCIENCE

A social science review was completed by Katherine Margolis on March 24, 2016.

[5] An addendum review was completed on May 1, 2018, to clarify that the characterizing flavor of the predicate tobacco product is "none." The addendum review does not change the conclusion of the initial grandfather determination dated March 30, 2016.

The social science review concludes that the new tobacco product has different characteristics compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health from a social science perspective. The review identified the following difference between the new and predicate tobacco products:

- 25% increase in package quantity (from 100 to 125 rolling papers)

The review concludes that there is no available scientific evidence on the influence that the number of rolling papers has on consumer perceptions of harm or use intentions to indicate that an increase of this magnitude would cause the new tobacco product to raise different questions of public health from a social science perspective. Therefore, the review concludes that the differences between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from a social science perspective.

Moreover, the Office of Science (OS) prepared a memorandum[6] summarizing its current thinking on product quantity changes, which further supports OS' determination that, at this time, changes in tobacco product quantity do not cause new tobacco products to raise different questions of public health. Consequently, the change in product quantity does not cause the new tobacco product to raise different questions of public health from a social science perspective.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Hans Rosenfeldt, Ph.D. on May 15, 2018. The FONSI was supported by an environmental assessment prepared by FDA on May 15, 2018.

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and predicate tobacco products are identical except for a 25% increase in package quantity (from 100 to 125 rolling papers).

The social science review and the finalized memorandum[6] conclude that based on OS's experience and the currently available evidence, the difference in product quantity does not cause the new tobacco product to raise different questions of public health. I concur with this conclusion.

The predicate tobacco product meets statutory requirements because it was determined that it is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

The new tobacco product is currently in compliance with the FD&C Act.

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

[6] *See* memorandum on product quantity changes, dated December 7, 2017.

An SE order letter should be issued for the new tobacco product in SE0012826, as identified on the cover page of this review.