Technical Project Lead (TPL) Review: SE0011188

SE0011188: Ventura Whites	
Package Type	Booklet
Package Quantity	200 papers
Length	70 mm
Width	39 mm
Characterizing Flavor[1]	None
Attributes	
Applicant	Republic Tobacco, LP
Report Type	Regular Product Quantity Change
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. 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: 2017.08.11 07:57:21 -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: 2017.08.11 08:56:27 -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 to compare with the new tobacco product:

Ventura Whites	
Package Type	Booklet
Package Quantity	32 papers
Length	70 mm
Width	39 mm
Characterizing Flavor[2]	None

The predicate tobacco product is manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On April 2, 2015, FDA received a Product Quantity Change SE Report from Republic Tobacco, LP. FDA issued an Acknowledgment letter to the applicant on April 22, 2015. On May 6, 2015, FDA requested additional information to uniquely identify the new and predicate tobacco products via teleconference. In response, the FDA received amendment (SE0011758) on May 12, 2015. The Office of Compliance and Enforcement requested information from the applicant on May 28, 2015, and the applicant responded with an amendment (SE0011919), received on June 4, 2015. FDA issued a Preliminary Finding letter on July 15, 2016. The applicant responded with amendment SE0013570, received by FDA on August 11, 2016. FDA issued a Preliminary Finding letter on April 25, 2017. The applicant responded with amendment SE0014086, received by FDA on May 15, 2017.

Product Name	SE Report	Amendments
Ventura Whites	SE0011188	SE0011758 SE0011919 SE0013570 SE0014086

1.3. SCOPE OF REVIEW

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

[2] As provided by applicant's certification statement. FDA does not conduct substantive scientific review to evaluate the information contained in the applicant's certification statement.

2. REGULATORY REVIEW

A regulatory review was completed by Sarah Webster on July 15, 2016.

The final 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 as of February 15, 2007). The OCE review dated June 16, 2015, 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.

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 July 27, 2017, 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 discipline:

4.1. SOCIAL SCIENCE

Social science reviews were completed by David Portnoy on August 5, 2015, and Anh Nguyen on September 26, 2016.

The final 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 product: an increase of product quantity from 32 papers to 200 papers (a 525% difference). Based on the scientific literature the applicant provided, the reviewer concludes that cigarette rolling papers are likely usage-invariant, low convenience, and low salience products. As a result, it is not likely that stockpiling or increasing the quantity in one's possession impacts consumer use. Therefore from a social science perspective, the difference in portion count between the new and predicate tobacco products does not cause the new tobacco product to raise different questions of public health.

For previous SE Reports for cigarette rolling papers that included a change in product quantity, given the relatively small magnitude of change, it was

determined that the new products did not raise different questions of public health. Accordingly, there was no need to assess more generally how changes in the quantity of cigarette rolling papers impact consumer perception and use. Given the magnitude of change here, a 525% difference, the social science reviews considered that question.

As described in the first social science review, there is evidence from research studies on other consumer products suggesting that when individuals are presented with a larger quantity of a product they increase consumption. FDA's Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (3d Edition) explains that larger product quantities can potentially reduce cessation behaviors and increase tobacco product use among current users. However, when that evidence is viewed in the context of all of the evidence provided in this SE Report, as well as FDA's general experience reviewing SE Reports, based on the current state of the evidence, for the class of products at issue here—cigarette rolling papers—an increase in product quantity would not cause a new product to raise different questions of public health. As described in the final social science review, for consumer products that are "usage-invariant" (*i.e.*, products which have price insensitive demand functions), "low convenience" (*i.e.*, products that require preparation and for which consumption costs time, comfort, and effort), and "low salience" (*i.e.*, products that are not noticeable, easily remembered, or recalled), increasing the product quantity generally would not impact consumer use. Given the likelihood that cigarette rolling papers are usage-invariant (since there is no benefit of using an increased number of cigarette rolling papers per quantity of RYO tobacco), low convenience (since they must be used with other products and require additional preparation before consumption), and low salience (since they are not highly visible, requiring little storage space), I find that, based on the current state of the evidence, an increase of product quantity from 32 papers to 200 papers does not cause the new product to raise different questions of public health.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on August 8, 2017. The FONSI was supported by an environmental assessment prepared by FDA on August 8, 2017.

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and predicate tobacco products are identical except for a change in product quantity from 32 rolling papers to 200 rolling papers.

The final social science review concludes that this difference in product quantity does not cause the new tobacco product to raise different questions of public health. I concur with the conclusion of the final social science review.

The predicate tobacco product meets statutory requirements because it was determined to be a grandfathered product (i.e., was commercially marketed in the United States 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.

An SE order letter should be issued for the new tobacco product in SE0011188 as identified on the cover page of this review.