Technical Project Lead (TPL) Review: SE0013890

SE0013890: Job Organic Hemp Single Wide	
Package Type	Booklet
Package Quantity	50 papers
Length	69 mm
Width	36 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. 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):

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Date: 2017.08.17 13:15:11 -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: 2017.08.17 14:07:50 -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:

SE0013890: Job Organic Hemp Single Wide	
Product Name	OCB Organic Hemp Single Wide
Package Type	Booklet
Package Quantity	100 papers
Length	69 mm
Width	36 mm
Characterizing Flavor	None

The predicate tobacco product is manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On January 31, 2017, FDA received a Product Quantity Change SE Report from Republic Tobacco, LP. An Acceptance review was completed on February 7, 2017, and the submission was determined to be administratively complete. FDA issued an Acknowledgment letter to the applicant on February 7, 2017. After the first round of scientific review, FDA issued a Preliminary Finding letter on May 11, 2017 containing environmental deficiencies identified in the SE Report. The applicant responded with amendment SE0014099.

Product Name	SE Report	Amendments
Job Organic Hemp Single Wide	SE0013890	SE0014099

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

Regulatory reviews were completed by Maria Suarez on February 7, 2017 and Sarah Webster on August 17, 2017.

The reviews conclude that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The predicate tobacco product in SE0013890 was determined to be substantially equivalent by FDA under SE0003297. Therefore, this product is an eligible predicate tobacco product.

The Office of Compliance and Enforcement (OCE) 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 August 3, 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

A social science review was completed by James Henrie on March 16, 2017.

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:

- The new tobacco product has a 50% decrease in product quantity

The review states that based on the scientific literature provided by the applicant and identified by the reviewer, cigarette rolling papers are likely usage-invariant, low convenience, and low salience products. As a result, the decrease in rolling paper product quantity is not likely to impact consumer use of the product. Therefore, the differences in product characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health.

As explained in FDA's Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (3d Edition), smaller product quantities may allow for increased product uptake due to lower barriers to trying the product, are associated with lower product harm perceptions, and reduce product costs or increase product availability, all of which may affect use intentions and behavior, including initiation among youth. However, as explained below, I find that for the type of product in this SE Report, a cigarette rolling paper, a decrease in product quantity would not cause a new tobacco product to raise different questions of public health.

First, based on FDA's experience and knowledge, it is very unlikely that youth would initiate tobacco use with the product that is the subject of this SE Report. This is because cigarette rolling papers require other tobacco products like tobacco filler and filters in order to be assembled into a finished product that is ready for use. Further, there is currently no available scientific evidence specific to cigarette rolling papers showing that this minor change would influence consumer perceptions of harm or use intentions. Second, as noted by the social science reviewer, scientific literature suggests that 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), decreasing the product quantity generally would not impact consumer use. Similarly, a decrease in the product quantity of usage-invariant, low convenience, and low salience products also generally would not impact initiation, including initiation among youth. A decrease in product quantity for a usage-invariant product generally would not affect initiation because youth generally would not initiate despite a corresponding decrease in price. A decrease in product quantity for a low convenience product generally would not affect initiation because, as explained above, youth generally would not initiate if product consumption continues to require additional time and effort to use the product. A decrease in product quantity for a low salience product generally would not affect youth initiation because the product remains not noticeable, easily remembered, or recalled. There is a high likelihood that cigarette rolling papers are usage-invariant (since there is no benefit of using an increased number of 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). Based on the foregoing, as well as FDA's general experience reviewing SE Reports for this type of product, I find that, based on the current state of the evidence, a decrease in product quantity from 100 to 50 rolling papers does not cause the new tobacco product to raise different questions of public health.

The applicant provided both a health information summary and a statement. The review also evaluated the health information summary and determined that it did not violate section 911 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 August 15, 2017. The FONSI was supported by an environmental assessment prepared by FDA on August 15, 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 50 rolling papers to 100 rolling papers (50% decrease).

The 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 social science review.

The predicate tobacco product was determined to be substantially equivalent by FDA under SE0003297.

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 SE0013890 as identified on the cover page of this review.