Technical Project Lead (TPL) Review: SE0012326 and SE0012327

SE0012326: OCB Yellow Cigarette Papers with Tips	
Package Type	Booklet
Package Quantity	32 rolling papers and 32 tips
Paper Length	109 mm
Paper Width	44 mm
Paper Characterizing Flavor[1]	None
Tip Length	55 mm
Tip Width	20 mm
Tip Characterizing Flavor[1]	None
SE0012327: OCB Slim Long Cigarette Papers with Tips	
Package Type	Booklet
Package Quantity	50 rolling papers and 50 tips
Paper Length	77 mm
Paper Width	44 mm
Paper Characterizing Flavor[1]	None
Tip Length	40 mm
Tip Width	20 mm
Tip Characterizing Flavor[1]	None
Common Attributes of SE Reports	
Applicant	Republic Tobacco, LP
Report Type	Regular Product Quantity Change
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Co-Package: Rolling papers and paper tips
Recommendation	
Issue Substantially Equivalent (SE) orders.	

[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: 2017.11.09 14:27:01 -05'00'

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: 2017.11.09 15:57:10 -05'00'

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

TABLE OF CONTENTS

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The predicate tobacco products have identical properties to the corresponding new tobacco products except for product quantity. The predicate tobacco products have the following product quantities:

SE0012326: OCB Yellow Cigarette Papers with Tips	
Product Quantity	24 rolling papers and 24 tips
SE0012327: OCB Slim Long Cigarette Papers with Tips	
Product Quantity	24 rolling papers and 24 tips

The predicate tobacco products are manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On September 1, 2015, FDA received two Product Quantity Change SE Reports from Republic Tobacco, LP. FDA issued Acknowledgment letters to the applicant on September 18, 2015. On September 18, 2015, FDA held a teleconference with the applicant and requested additional information to uniquely identify the new and predicate tobacco products. On September 25, 2015, the applicant submitted a response (SE0012417 and SE0012418). On March 25, 2016, FDA held another teleconference with the applicant and, based on an environmental review dated the same day, requested additional information about the new and predicate tobacco products. The applicant submitted a response on March 29, 2016 (SE0013287). FDA held another teleconference with the applicant on June 20, 2016, with clarifying questions. On June 23, 2016, the applicant submitted a response (SE0013463). On October 14, 2016, FDA issued Correction letters for the Acknowledgment letters to capture the additional properties for the new and predicate tobacco products.

Product Name	SE Report	Amendments
OCB Yellow Cigarette Papers with Tips	SE0012326	SE0012417 SE0013287 SE0013463
OCB Slim Long Cigarette Papers with Tips	SE0012327	SE0012418 SE0013287 SE0013463

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 Ryan Nguy on September 18, 2015, and by Sarah Webster on November 6, 2017.

The final review concludes 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 are grandfathered products (i.e., were commercially marketed as of February 15, 2007). The OCE reviews dated October 29, 2015, and November 2, 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.

OCE also completed reviews 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 FD&C Act). The OCE reviews dated April 11, 2016; July 27, 2016; October 14, 2016; April 21, 2017; and October 13, 2017, conclude that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

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 Rhonda Moore on November 2, 2015.

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

- SE0012326: Increase of 33.33% (24 rolling papers and tips to 32 rolling papers and tips)
- SE0012327: Increase of 108% (24 rolling papers and tips to 50 rolling papers and tips)

The social science reviewer states that there is currently no available scientific evidence that these changes in the number of rolling papers and tips per booklet influence consumer perceptions of harm or use intentions. Further, the reviewer states that evidence from other consumer products suggests that these changes in the number of rolling papers and tips per booklet would not cause the new tobacco products to raise different questions of public health from a social science perspective.

As explained in FDA's Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (3d Edition), increasing product quantity can potentially reduce cessation behaviors and increase tobacco product use among current users. However, when that evidence is viewed in the context of the evidence provided in these SE Reports, as well as other scientific literature and FDA's general experience reviewing SE Reports, based on the current state of the evidence, for the class of products at issue here—RYO cigarette rolling papers and tips—an increase in product quantity would not

cause a new tobacco product to raise different questions of public health. Scientific literature suggests that for consumer products that are "usage-invariant" (i.e., products which have price insensitive demand functions), increasing the product quantity generally would not impact consumer use. Relatedly, for consumer products that are "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 also generally would not impact consumer use.[2] Given the likelihood that RYO cigarette rolling papers and tips are usage-invariant (since there is no benefit of using an increased number of rolling papers and tips 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 of 33% or 108% does not cause the new tobacco products 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 September 20, 2017. The FONSI was supported by an environmental assessment prepared by FDA on September 20, 2017.

6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate tobacco products are identical except for the following product quantity changes:

- SE0012326: Increase of 33.33% (24 rolling papers and tips to 32 rolling papers and tips)
- SE0012327: Increase of 108% (24 rolling papers and tips to 50 rolling papers and tips)

The social science review concludes that these differences in product quantity do not cause the new tobacco products to raise different questions of public health. I concur with the conclusion of the social science review.

The predicate tobacco products meet statutory requirements because it was determined that they are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007).

The new tobacco products are currently in compliance with the FD&C Act.

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 SE0012326 and SE0012327 as identified on the cover page of this review.

[2] Chandon, P. & Wansink, B. (2002). When are stockpiled products consumed faster? A convenience-salience framework of postpurchase consumption incidence and quantity. Journal of Marketing Research, 321-335.