Technical Project Lead (TPL) Review: SE0011134

SE0011134: Top King Size	
Package Type	Pouch
Package Quantity	100 filters
Length	18 mm
Diameter	7.8 mm
Ventilation	None
Characterizing Flavor[1]	None
Attributes	
Applicant	Republic Tobacco, LP
Report Type	Regular Product Quantity Change
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Filter
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 12:44:20 -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 14:07:05 -04'00'

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant certifies that the predicate tobacco product is identical to the new tobacco product except for product quantity. According to the applicant, the predicate tobacco product has the following characteristics:

SE0000271: Top King Size	
Package Quantity	200 filters
Length	18 mm
Diameter	7.8 mm
Ventilation	None
Characterizing Flavor	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. On May 11, 2015, the applicant submitted a response (SE0011758). On November 4, 2015, FDA contacted the applicant to request clarification of the new tobacco product name. The applicant submitted a response (SE0012589) on November 5, 2015. On February 17, 2016, FDA issued an Advice/Information Request letter to the applicant to state that FDA intends to issue its order on the new product only after it has completed its review of the original "provisional" SE Report because products that are the subject of "provisional" SE Reports may not serve as predicate tobacco products under the Federal Food Drug and Cosmetic Act unless they have been previously found substantially equivalent. After an environmental review was conducted on March 10, 2017, FDA issued a Preliminary Finding letter on May 12, 2017. The Preliminary Finding letter identified environmental deficiencies in the applicant's SE Report. The applicant submitted a response (SE0014101) on May 19, 2017. FDA emailed the applicant with clarifying questions on June 12, 2017, and the applicant submitted a response (SE0014145) on the same day.

Product Name	SE Report	Amendments
Top King Size	SE0011134	SE0011758 SE0012589 SE0014101 SE0014145

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 Ryan Nguy on April 22, 2015, and Sarah Webster on February 16, 2016.

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

3. COMPLIANCE REVIEW

The predicate tobacco product in SE0011134 was previously found to be substantially equivalent by FDA under SE0000271. Therefore, the predicate tobacco product is an eligible predicate tobacco product.

The Office of Compliance and Enforcement (OCE) completed reviews 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 reviews dated June 16, 2015, August 6, 2015, October 14, 2015, January 13, 2016, and July 27, 2017 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 David Portnoy on August 5, 2015.

The social science review concludes that the new tobacco product has different characteristics compared to the predicate tobacco product but that the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following difference between the new and predicate tobacco products: a decrease of product quantity from 200 filters to 100 filters (50%). The social science reviewer states that there is currently no available scientific evidence that this minor change in the number of filters per pouch influences consumer perceptions of harm or use intentions. Further, the reviewer states that evidence from other consumer products suggests that this change in the number of filters per pouch would not cause the new tobacco product 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), 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 filter, 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 filters require other tobacco products like tobacco filler and paper in order to be assembled into a finished product that is ready for use. Further, I agree with the social science reviewer that there is currently no available scientific evidence specific to filters showing that this minor decrease in product quantity for cigarette filters would influence consumer perceptions of harm or use intentions. Second, although not evaluated by the social science reviewer for this particular SE Report, 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), increasing 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 consumer use and behavior, 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 also 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 filters are usage-invariant (since there is no benefit of using an increased number of filters 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 200 to 100 filters does not cause the new tobacco 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 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 200 filters to 100 filters.

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 meets statutory requirements because it was determined to be substantially equivalent by FDA under SE0000271.

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 SE0011134 as identified on the cover page of this review.