Technical Project Lead (TPL) Review: SE0000271

SE0000271: Top King Size	
Package Type	Bag
Package Quantity	200 filters
Length	18 mm
Diameter	7.8 mm
Filter Ventilation	None
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Republic Tobacco, LP
Report Type	Provisional
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Filter
Recommendation	
Issue a Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2017.04.27 11:49:15 -04'00'

Colleen K. Rogers, Ph.D.
Director
Division of Product 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: 2017.04.28 08:07:40 -04'00'

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

TABLE OF CONTENTS

BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0000271	Top King Size
Product Name	Top Cig Filter Tips
Package Type	Bag
Package Quantity	100 filters
Length	15 mm
Diameter	7.8 mm
Filter Ventilation	None
Characterizing Flavor	None

The predicate tobacco product is a roll-your-own filter manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant submitted the SE Report on March 16, 2011. An Advice/Information (A/I) Request letter was sent to the applicant on September 27, 2012. On October 23, 2012, the applicant responded to the A/I letter by submitting an amendment (SE0005051). On September 18, 2015, the applicant responded to an information request (SE0012372). FDA issued a Preliminary Finding letter on January 5, 2016 to the applicant. On January 29, 2016, the applicant responded to the Preliminary Finding letter by submitting an amendment to the SE Report (SE0012827). Following scientific review of the SE Report, FDA issued an A/I letter to the applicant on April 28, 2016. The applicant responded to the A/I letter by submitting an amendment to the SE Report (SE0013464) on June 23, 2016. On August 5, 2016, FDA requested additional information and the applicant responded by submitting an amendment (SE0013565) on August 8, 2016.

Product Name	SE Report	Amendments
Top King Size	SE0000271	SE0005051 SE0012372 SE0012827 SE0013464 SE0013565

1.3. SCOPE OF REVIEW

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

REGULATORY REVIEW

Regulatory reviews were completed by Dan Gonski on September 27, 2012, and Sarah Lee on November 25, 2013.

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

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 September 15, 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.

SCIENTIFIC REVIEW

Scientific reviews were completed by the Office of Science (OS) for the following disciplines:

1.4. ENGINEERING

Engineering reviews were completed by Michael Morschauser on March 30 and August 9, 2016.

The new tobacco product has the following key differences in product design compared to the predicate tobacco product:

- Increase in length from 15 mm to 18 mm (20%)
- Increase in pressure drop from (b) (4)

The final engineering review concludes that the new tobacco product has different characteristics related to product design compared to the predicate tobacco product but the differences do not cause the new tobacco product to raise different questions of public health. Filter pressure drop increased in the new tobacco product in proportion to the increase in filter length. An increase in either filter pressure drop or filter length would lead to increased filter efficiency, which would reduce exposure to smoke constituents. Because the new tobacco product has an increase in both length and pressure drop and no other filter parameters have changed, the increases in length and pressure drop do not raise different questions of public health. Therefore, the differences in characteristics related to product design between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health.

1.5. SOCIAL SCIENCE

A social science review was completed by Katherine Margolis on April 5, 2016, and an addendum review was completed by Katherine Margolis on February 27, 2017.

The new tobacco product has the following key differences compared to the predicate tobacco product:

- Increase in length from 15 mm to 18 mm (20%)
- Increase in package quantity from 100 to 200 filters (100%)

The final social science review concludes that the new tobacco product has different characteristics related to consumer perception compared to the predicate tobacco product but the differences do not cause the new tobacco product to raise different questions of public health. Since the new tobacco product is longer than the predicate tobacco product, the size of the filter could affect consumer perceptions. However, there is no currently available scientific evidence on the influence of the size of filters on consumer perceptions or use intentions to indicate that such an increase in product size would cause the new product to raise different questions of public health from a social science perspective. The change from 100 filters in the predicate product to 200 filters in the new product represents a 100% increase in package quantity. However, there is no currently available scientific evidence on the influence that the number of filters has on consumer perceptions of harm or use intentions to indicate that an increase of this magnitude would cause the new product to raise different questions of public health from a social science perspective. Therefore, the differences in product characteristics related to consumer perception and use between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health.

ENVIRONMENTAL DECISION

Issuance of an SE order for SE0000271 falls within a class of actions that are ordinarily categorically excluded from environmental assessment under 21 CFR 25.35(a). To the best of our knowledge, no extraordinary circumstances exist that would preclude application of this categorical exclusion. FDA concludes that categorical exclusion is warranted and no environmental assessment or environmental impact statement is required. A memo describing this environmental decision was signed by Hoshing Chang on February 9, 2017.

CONCLUSION AND RECOMMENDATION

The following are the key differences in characteristics between the new and predicate tobacco products:

- Increase in length from 15 mm to 18 mm (20%)
- Increase in pressure drop from (b) (4)
- Increase in package quantity from 100 to 200 filters (100%)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. Filter pressure drop increased in the new tobacco product in proportion to the increase in filter length. An increase in either filter pressure drop or filter length would lead to increased filter efficiency, which would reduce exposure to smoke constituents. Because the new tobacco product has an increase in both length and pressure drop and no other filter parameters have changed, the increases in length and pressure drop do not raise different questions of public health. From a social science perspective, there is no currently available scientific evidence on the influence that filter length or package quantity has on consumer perceptions of harm or use intentions to indicate that increases of the magnitude seen in the SE Report would cause the new product to raise different questions of public health. Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health.

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

All of the scientific reviews conclude that the differences between the new and predicate tobacco products are such that the new tobacco product does not raise different questions of public health. I concur with these reviews and recommend that an SE order letter be issued.

FDA examined the environmental effects of finding this new tobacco product substantially equivalent and concludes that a categorical exclusion is warranted and no extraordinary circumstances exist which would require preparation of an environmental assessment or an environmental impact statement.

An SE order letter should be issued for the new tobacco product in SE0000271, as identified on the cover page of this review.