FDA U.S. FOOD & DRUG ADMINISTRATION

# Technical Project Lead (TPL) Review: SE0012177

| SE0012177: Top Silver King Size | |
|---|---|
| **Package Type** | Box |
| **Package Quantity** | 250 tubes |
| **Length** | 84 mm |
| **Diameter** | 8.1 mm |
| **Filter Ventilation** | 0% |
| **Characterizing Flavor**[1] | None |
| **SE Report Attributes** | |
| **Applicant** | Republic Tobacco, LP |
| **Report Type** | Product Quantity Change Regular |
| **Product Category** | Roll-Your-Own Tobacco |
| **Product Sub-Category** | Filtered Cigarette Tube |
| **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):**

Digitally signed by Colleen K. Rogers -S
Date: 2018.01.11 16:27:25 -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: 2018.01.11 16:50:11 -05'00'

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:

| SE0012177: Top Silver King Size | |
|---|---|
| **Product Name** | Top Silver King Size |
| **Package Type** | Box |
| **Package Quantity** | 200 tubes |
| **Length** | 84 mm |
| **Diameter** | 8.1 mm |
| **Filter Ventilation** | 0% |
| **Characterizing Flavor**[2] | None |

The predicate tobacco product is roll-your-own tobacco filtered cigarette tube manufactured by the applicant.

## 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On July 10, 2015, FDA received a Product Quantity Change SE Report from Republic Tobacco, LP. FDA issued an Acknowledgement letter to the applicant on July 20, 2015. FDA issued a Preliminary Finding letter identifying environmental assessment (EA) deficiencies for the SE Report on September 25, 2017. The applicant submitted a response (SE0014378) on October 17, 2017.

| Product Name | SE Report | Amendments |
|---|---|---|
| Top Silver King Size | SE0012177 | SE0014378 |

## 1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these SE Reports.

# 2. REGULATORY REVIEW

A regulatory review was completed by Ryan Nguy on July 15, 2015. The review concludes that the SE Report is administratively complete.

# 3. COMPLIANCE REVIEW

The predicate tobacco product in SE0012177 was previously determined to be substantially equivalent by FDA under SE0010369. Therefore, the predicate product is an eligible predicate tobacco product.

[2] 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.

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) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated January 10, 2018, concludes 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 Jennifer Bernat on August 20, 2015.

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 between the new and predicate tobacco products:

- 25% increase in package quantity (from 200 to 250 tubes)

The review concludes that there is no available scientific evidence on the influence that the number of tubes per box has on consumer perceptions of harm or use intentions to indicate that an increase of this magnitude would cause the new tobacco product to raise different questions of public health from a social science perspective. Therefore, the review concludes that the differences between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from a social science perspective.

Moreover, the Office of Science (OS) prepared a memorandum[3] summarizing its current thinking on product quantity changes, which further supports OS' determination that, at this time, changes in tobacco product quantity do not cause new tobacco products to raise different questions of public health. Consequently, the change in product quantity does not cause the new tobacco product to raise different questions of public health from a social science perspective.

## 5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on January 11, 2018. The FONSI was supported by an environmental assessment prepared by FDA on January 11, 2018.

## 6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and predicate tobacco products are identical except for a 25% increase in package quantity (from 200 to 250 tubes).

[3] *See* memorandum on product quantity changes, dated December 7, 2017.

The social science review and the recently finalized memorandum[4] conclude that based on OS's experience and the currently available evidence, the difference in product quantity does not cause the new tobacco product to raise different questions of public health. I concur with this conclusion.

The predicate tobacco product meets statutory requirements because it was determined to be substantially equivalent by FDA under SE0010369.

Where an applicant supports a showing of SE by comparing the new tobacco product to a tobacco product that FDA previously found SE, in order to issue an SE order, FDA must find that the new tobacco product is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act).

The predicate tobacco product in SE0012177 was previously determined to be substantially equivalent by FDA under SE0010369. Comparison of the new tobacco product in SE0012177 to the grandfathered tobacco product in SE0010369 (Top Regular King Size) reveals the following key differences in characteristics:

- Increase in cellulose in cigarette paper, tipping paper, and plugwrap
- Increase in [redacted] in cigarette paper
- Addition of starch to cigarette paper and tipping paper
- Addition of [redacted] and [redacted] increase in [redacted] in tipping paper
- Removal of [redacted] from plugwrap
- Increase in c[redacted] in filter acetate tow
- Increase in triacetin in filter acetate tow
- Decreased denier per filament
- Increased filter density
- Increased filter pressure drop
- Increased base paper basis weight
- Increased base paper porosity
- Decreased filter total denier
- Addition of silver ink and removal of black ink from tipping paper

The differences in characteristics listed above, other than the differences in product quantity, are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0010369. Therefore, these differences do not cause the new tobacco product in SE0012177 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in product quantity between the new tobacco product in SE0012177 and the grandfathered tobacco product do not cause the new tobacco product to raise different questions of public health. Therefore, whether comparing the new tobacco product in SE0012177 to the predicate or grandfathered tobacco product, the new tobacco product does not raise different questions of public health.

The new tobacco product is currently in compliance with the FD&C Act.

[4] *See* memorandum on product quantity changes, dated December 7, 2017.

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 SE0012177, as identified on the cover page of this review.