FDA U.S. FOOD & DRUG ADMINISTRATION

# Technical Project Lead (TPL) Review: SE0014367 and SE0014368

| SE0014367: Top Standard | |
|---|---|
| Package Type | Booklet |
| Package Quantity | 125 papers |
| Length | 70 mm |
| Width | 39 mm |
| Characterizing Flavor[1] | None |
| Additional Properties | Paper 1 |
| **SE0014368: Top Standard** | |
| Package Type | Booklet |
| Package Quantity | 125 papers |
| Length | 70 mm |
| Width | 39 mm |
| Characterizing Flavor[1] | None |
| Additional Properties | Paper 2 |
| **Common Attributes of SE Reports** | |
| Applicant | Republic Tobacco, LP |
| Report Type | Regular Product Quantity Change |
| Product Category | Roll-Your-Own Tobacco |
| Product Sub-Category | Rolling Paper |
| **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: 2018.04.03 12:27:33 -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: 2018.04.03 13:32:54 -04'00'

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

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# 1. BACKGROUND

## 1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

| **SE0014367: Top Standard** | |
|---|---|
| Product Name | Top Cig Paper 24's |
| Package Type | Booklet |
| Package Quantity | 100 papers |
| Length | 70 mm |
| Width | 39 mm |
| Characterizing Flavor[1] | None |
| **SE0014368: Top Standard** | |
| Product Name | Top Standard |
| Package Type | Booklet |
| Package Quantity | 100 papers |
| Length | 70 mm |
| Width | 39 mm |
| Characterizing Flavor[1] | None |

The predicate tobacco products are roll-your-own rolling papers manufactured by the applicant.

## 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On October 2, 2017, FDA received two product quantity change SE Reports from Republic Tobacco, LP. FDA issued an Acknowledgement letter to the applicant on October 11, 2017. FDA issued a Preliminary Finding letter on December 15, 2017, requesting additional information regarding the environmental assessment. The applicant's response to the December 15, 2017, Preliminary Finding letter was received on January 3, 2018 (SE0014457).

| Product Name | SE Report | Amendments |
|---|---|---|
| Top Standard | SE0014367 | SE0014457 |
| Top Standard | SE0014368 | |

## 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 Sarah Webster on October 11, 2017, and Nicholas Hasbrouck on March 21, 2018. The final reviews conclude that each SE Report is administratively complete.

The regulatory review found that the new tobacco products were uniquely identified. However, the new tobacco products have the same name, product category, product subcategory, package type, package quantity, length, width, and characterizing flavor. Accordingly, additional properties are needed to uniquely identify the new tobacco products. The rolling papers in the new tobacco products are comprised of different paper, which have different compositions.[2]

## 3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the predicate tobacco product in SE0014367 is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated November 3, 2017,[3] concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product in SE0014367 is grandfathered and, therefore, is an eligible predicate tobacco product.

The predicate tobacco product in SE0014368 was determined to be substantially equivalent by FDA under SE0012913. Therefore, the predicate tobacco product in SE0014368 is an eligible predicate tobacco product.

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 March 20, 2018, and April 3, 2018, conclude that the new tobacco products are 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 Rhonda Moore on December 4, 2017.

The social science review concludes that the new tobacco products have different characteristics from 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 difference between the new and corresponding predicate tobacco products:

- 25% increase in product quantity (from 100 to 125 rolling papers)

[2] The new tobacco product in SE0014367 is comprised of "paper 1," which is supplied by (b) (4) and contains the following ingredients (mg/sheet): (b) (4) (b) (4) . The new tobacco product in SE0014368 is comprised of "paper 2," which is supplied by (b) (4) and contains the following ingredients (mg/sheet) (b)(4) (b) (4) .

[3] An addendum review was completed on March 30, 2018, to clarify that the characterizing flavor of the predicate tobacco product is "none." Since the initial grandfather determination on November 3, 2017, was based on the same product characteristics apart from characterizing flavor, the addendum review does not change the conclusion of the initial determination.

The review concludes that the products are usage-invariant (since there is likely no perceived benefit to using an increased number of rolling papers per quantity of RYO tobacco); low convenience (since they require other products and additional preparation before use); and low salience (since they are small and require little storage space). Therefore, given the likelihood that the increase in product quantity does not impact consumer use, the review concludes that the differences between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a social science perspective.

Moreover, the Office of Science (OS) prepared a memorandum[4] 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 products 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 March 30, 2018. The FONSI was supported by an environmental assessment prepared by FDA on March 30, 2018.

## 6. CONCLUSION AND RECOMMENDATION

The product characteristics of the new and corresponding predicate tobacco products are identical except for a 25% increase in product quantity (from 100 to 125 rolling papers).

The social science review and the 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 products to raise different questions of public health. I concur with this conclusion.

The predicate tobacco product in SE0014367 meets statutory requirements because it was determined that it is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The predicate tobacco product in SE0014368 meets statutory requirements because it was previously determined to be substantially equivalent by FDA under SE0012913.

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 other than exclusively in test markets as of February 15, 2007 (see section 910(a)(2)(A)(i)(I) of the FD&C Act).

The predicate tobacco product in SE0014368 was previously determined to be substantially equivalent by FDA under SE0012913. Comparison of the new tobacco product in SE0014368 (Top

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

Standard) to the grandfathered product in SE0012913 (Top Cig Paper 24's) reveals the following differences in characteristics:

- 25% increase in product quantity (from 100 to 125 rolling papers)
- 7% increase in (b) (4) [redacted]
- 100% increase in (b) (4) [redacted]

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 SE0012913. The change in composition of the (b) (4) [redacted] (i.e., increases in (b) (4) [redacted]) is due to a change in paper supplier. Therefore, the differences in (b) (4) [redacted] do not cause the new tobacco product in SE0014368 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 SE0014368 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 SE0014368 to the predicate or grandfathered tobacco products, the new tobacco product does not raise different questions of public health.

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 SE0014367 and SE0014368, as identified on the cover page of this review.