

Technical Project Lead (TPL) Review: SE0012487-SE0012492

SE0012487: Top Silver 100 mm	
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	(b) (4)
Characterizing Flavor	None
SE0012488: Gambler Tubecut Silver King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	(b) (4)
Characterizing Flavor	None
SE0012489: Gambler Silver King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	(b) (4)
Characterizing Flavor	None
SE0012490: Gambler Tubecut Silver 100 mm	
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	(b) (4)
Characterizing Flavor	None
SE0012491: Gambler Silver 100 mm	
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	(b) (4)
Characterizing Flavor	None
SE0012492: Top Silver King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	(b) (4)
Characterizing Flavor	None

Common Attributes of SE Reports	
Applicant	Republic Tobacco, LP
Report Type	Regular
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Filtered Cigarette Tube
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2017.12.17 22:25:46 -05'00'

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: 2017.12.18 08:07:17 -05'00'

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:

SE0012487	Top Silver 100 mm
Product Name	Top Silver 100 mm
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	(b) (4)
Characterizing Flavor	None
SE0012488	Gambler Tubecut Silver King Size
Product Name	Gambler Tubecut Silver King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	(b) (4)
Characterizing Flavor	None
SE0012489	Gambler Silver King Size
Product Name	Gambler Silver King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	(b) (4)
Characterizing Flavor	None
SE0012490	Gambler Tubecut Silver 100 mm
Product Name	Gambler Tubecut Silver 100 mm
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	(b) (4)
Characterizing Flavor	None
SE0012491	Gambler Silver 100 mm
Product Name	Gambler Silver 100 mm
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	(b) (4)
Characterizing Flavor	None

SE0012492	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	(b) (4)
Characterizing Flavor	None

The predicate tobacco products are all roll-your-own tobacco filtered cigarette tubes manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On October 13, 2015, FDA received 6 Regular SE Reports from the applicant. FDA issued acknowledgement letters on October 20, 2015. An amendment with environmental information was received on February 3, 2016 (SE0012851).

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 Sarah Webster on October 19, 2015.

The review concludes that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

All of the new tobacco products rely on predicate tobacco products that were previously found Substantially Equivalent (SE). As described in an October 21, 2015, memo from Sarah Webster, if the predicate product used in the SE Report is a product previously found SE, the Office of Compliance and Enforcement (OCE) does not perform a Predicate Eligibility review. All of the predicate tobacco products received SE orders on March 27, 2015, and are listed in the table below. All of the predicate products have been previously found SE to another product and as such are eligible predicate tobacco products.

Product Name	SE Report	Predicate Product SE Report
Top Silver 100 mm	SE0012487	SE0010368
Gambler Tubecut Silver King Size	SE0012488	SE0010365
Gambler Silver King Size	SE0012489	SE0010422
Gambler Tubecut Silver 100 mm	SE0012490	SE0010366
Gambler Silver 100 mm	SE0012491	SE0010367
Top Silver King Size	SE0012492	SE0010369

OCE 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 January 7 and 13, 2016; April 11, 2016; July 27, 2016; October 14, 2016; February 13, 2017; April 21, 2017; and October 31, 2017, conclude that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

Scientific reviews¹ were completed by the Office of Science (OS) for the following disciplines:

4.1. CHEMISTRY

A chemistry review was completed by Todd Cecil on December 3, 2015.

The chemistry review concludes that the new tobacco products have different characteristics compared to the predicate tobacco products, but the differences do not cause the new tobacco products to raise different questions of public health from a chemistry perspective. The new tobacco products contain 0.015 mg/tube² less silver ink applied to the tipping paper than the predicate tobacco products. The new tobacco products contain one silver band and one silver brand logo, which are pre-printed on the tipping paper by the supplier. The predicate tobacco products contain two silver bands pre-printed on the tipping paper by the supplier and a silver brand logo (comprised of 0.015 mg/tube silver ink) subsequently added by the applicant to the pre-printed tipping paper. The amount and composition of silver ink used by the tipping paper supplier for the new and predicate tobacco products is identical. Therefore, by eliminating the applicant-applied silver brand logo, the new tobacco products contain 0.015 mg/tube less silver ink than the corresponding predicate tobacco products. Because the new tobacco products use a lower amount of silver ink than the predicate tobacco products, and the ink used on the new tobacco products is not different than the ink used on the predicate tobacco products, the changes do not cause the new tobacco products to raise different questions of public health. Therefore, the differences in characteristics related to product composition between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health from a chemistry perspective.

¹ Because the differences in characteristics were limited to the ink used on the tipping paper, the only scientific review needed was chemistry.

² The chemistry review contains a typographical error and lists the difference as 0.0015 mg/tube.

It should be noted that the chemistry review states that the applicant claims the predicate and corresponding new tobacco products have the same characteristics. The applicant's basis for a claim of substantial equivalence is not clearly stated, but appears to be that the predicate and corresponding new tobacco products have different characteristics but the new tobacco products do not raise different questions of public health (sec. 910(a)(3)(A)(ii)). The applicant states, "[t]he [new] RYO tobacco product is "substantially equivalent" to the predicate [product] because all of the characteristics are "the same" in both products and any differences do not "raise different questions of public health."" The applicant further states, "[t]o the extent there are any apparent differences between the [new] and predicate product, we believe these differences may not constitute "modifications" that make the current product a "new tobacco product."" Due to this unclear language, the chemistry review states the claim as same characteristics (sec. 910(a)(3)(A)(i)). Because the new tobacco products differ from the corresponding predicate tobacco products in the amount and application of tipping paper ink, FDA has determined that the claim is that the predicate and corresponding new tobacco products have different characteristics but the new tobacco products do not raise different questions of public health.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on October 31, 2017. The FONSI was supported by an environmental assessment prepared by FDA on October 31, 2017.

6. CONCLUSION AND RECOMMENDATION

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

- The new products have 0.015 mg/tube less silver ink applied to the tipping paper as compared to the corresponding predicate products

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The reduction in ink content is due to the elimination of the applicant-applied brand logo to the tipping paper. There is also a change to the tipping paper (pre-printed by the supplier): A silver band is replaced with a brand logo on the new tobacco products using an equivalent amount and type of ink. Because the new tobacco products use a lower amount of silver ink than the predicate tobacco products, and the ink used on the new tobacco products is not different than the ink used on the predicate tobacco products, the changes do not cause the new tobacco products to raise different questions of public health. Furthermore, the change in ink is located on the tipping paper, which is not burned; therefore, this change is unlikely to lead to an increase in HPHCs. Also, the applicant states that the ink is non-soluble, thus will not be consumed by the user or potentially allow ingestion of the ink. Therefore, the differences in characteristics between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

The predicate tobacco products meet statutory requirements because they were determined to be substantially equivalent by FDA under SE0010365-SE0010369 and SE0010422. 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 products in SE0012487, SE0012490, and SE0012491 were previously determined to be substantially equivalent by FDA under SE0010368, SE0010366, and SE0010367, respectively. Comparison of the new tobacco products to the grandfathered product (Top Gold 100 mm) in SE0010366-SE0010368 reveals that the new tobacco products have the following differences in characteristics from Top Gold 100 mm, the grandfathered tobacco product:

- Decrease in [REDACTED] in cigarette paper, tipping paper, and plugwrap
- (b) (4) in triacetin in filter acetate tow
- Decreased [REDACTED] (b) (4)
- Increased [REDACTED] (from [REDACTED])
- Increased [REDACTED] (from [REDACTED])
- Increased [REDACTED] (from [REDACTED])
- Addition of silver ink and removal of gold ink from tipping paper
- Addition of lubricants to filter

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 SE0010368, SE0010366, and SE0010367. Therefore, these differences do not cause the new tobacco products in SE0012487, SE0012490, and SE0012491 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in product quantity between the new tobacco products in SE0012487, SE0012490, and SE0012491 and the grandfathered tobacco product do not cause the new tobacco products to raise different questions of public health. Therefore, whether comparing the new tobacco products in SE0012487, SE0012490, and SE0012491 to the predicate or grandfathered tobacco products, the new tobacco products do not raise different questions of public health.

The predicate tobacco products in SE0012488, SE0012489, and SE0012492 were previously determined to be substantially equivalent by FDA under SE0010365, SE0010422, and SE0010369, respectively. Comparison of the new tobacco products to the grandfathered products (Gambler Regular King Size in SE0010365 and SE0010422, and Top Regular King Size in SE0010369) reveals that the new tobacco products have the following differences in characteristics from Gambler Regular King Size and Top Regular King Size, the grandfathered tobacco products:

- Increase in [REDACTED] in cigarette paper, tipping paper, and plugwrap
- Increase in (b) (4) [REDACTED] in cigarette paper
- Addition of (b) (4) [REDACTED] to cigarette paper and tipping paper
- Addition of (b) (4) [REDACTED] in tipping paper
- Removal of (b) (4) [REDACTED] from plugwrap
- Increase in (b) (4) [REDACTED] in filter acetate tow
- (b) (4) in triacetin in filter acetate tow
- Decreased [REDACTED] (from [REDACTED])
- Decreased (b) (4) [REDACTED] (from (b) (4) [REDACTED])
- Increased (b) (4) [REDACTED] (from (b) (4) [REDACTED])

- Increased [REDACTED] (from [REDACTED])
- Increased [REDACTED] (from [REDACTED])
- Increased [REDACTED] (from [REDACTED])
- 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 SE0010365, SE0010369, and SE0010422. Therefore, these differences do not cause the new tobacco products in SE0012488, SE0012489, and SE0012492 to raise different questions of public health. Additionally, for the same reasons as discussed above, the differences in product quantity between the new tobacco products in SE0012488, SE0012489, and SE0012492 and the grandfathered tobacco products do not cause the new tobacco products to raise different questions of public health. Therefore, whether comparing the new tobacco products in SE0012488, SE0012489, and SE0012492 to the predicate or grandfathered tobacco products, the new tobacco products do not raise different questions of public health.

All of the new tobacco products are currently in compliance with the FD&C Act. In addition, the scientific review concludes that the differences between the new and corresponding predicate tobacco products are such that the new tobacco products do not raise different questions of public health. I concur with this review and recommend that SE order letters be issued.

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 SE0012487-SE0012492, as identified on the cover page of this review.