

**Technical Project Lead (TPL) Review:
SE0010365-SE0010369 and SE0010422**

SE0010365: Gambler Tubecut Silver King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010366: Gambler Tubecut Silver 100mm	
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010367: Gambler Silver 100mm	
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010368: Top Silver 100mm	
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010369: Top Silver King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0010422: Gambler Silver King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Common Attributes of SE Reports	
Applicant	Republic Tobacco L.P.
Report Type	Regular
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Filter cigarette tube
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S
Date: 2015.03.26 09:52:13 -04'00'

Matthew R. Holman, 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 David Ashley -S
Date: 2015.03.26 11:34:57 -04'00'

David L. Ashley, Ph.D.
RADM, U.S. Public Health Service
Director
Office of Science

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0010365: Gambler Tubecut Silver King Size	
Product Name	Gambler Regular King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010366: Gambler Tubecut Silver 100mm	
Product Name	Top Gold 100mm
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010367: Gambler Silver 100mm	
Product Name	Top Gold 100mm
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010368: Top Silver 100mm	
Product Name	Top Gold 100mm
Package Type	Box
Package Quantity	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

SE0010369: Top Silver King Size	
Product Name	Top Regular King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
SE0010422: Gambler Silver King Size	
Product Name	Gambler Regular King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None

The predicate tobacco products are roll-your-own (RYO) tobacco filtered cigarette tubes manufactured by Republic Tobacco L.P.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On April 3, 2014, Republic Tobacco, LP submitted these SE Reports. On May 8, 2014, the applicant submitted responses requested by the Office of Compliance and Enforcement (OCE) to confirm the identity of the predicate tobacco product in SE0010422. On June 6, 2014, FDA issued the applicant a Scientific Advice/Information request letter, and the applicant submitted an amendment in response on July 22, 2014. On June 26, 2014, the applicant submitted an amendment stating the predicate tobacco products in SE0010366-SE0010368 were previously found substantially equivalent. On August 28, 2014, the applicant resubmitted a legible copy of Exhibit 20 in the July 22, 2014, amendment. A Preliminary Finding letter was issued on October 21, 2014, and the applicant submitted an amendment in response on November 18, 2014. On December 5, 2014, FDA sent an email to the applicant requesting additional product design information, and the applicant submitted an amendment in response on December 15, 2014. On January 14, 2015, FDA sent an email to the applicant requesting information related to the Environmental Assessment (EA). A teleconference was held on January 15, 2015, to clarify any questions the applicant regarding the requested EA information. FDA received an amendment with the requested EA information on January 20, 2015. Lastly, on January 30, 2015, FDA received an amendment containing images of product packaging, which was requested by FDA during a January 27, 2015, teleconference.

Product Name	SE Report	Amendments
Gambler Tubecut Silver King Size	SE0010365	SE0010593 SE0010660 SE0010754 SE0010790 SE0010839
Gambler Tubecut Silver 100mm	SE0010366	SE0010551 SE0010593 SE0010660 SE0010754 SE0010790 SE0010839
Gambler Silver 100mm	SE0010367	SE0010551 SE0010593 SE0010660 SE0010754 SE0010790 SE0010839
Top Silver 100mm	SE0010368	SE0010551 SE0010593 SE0010660 SE0010754 SE0010790 SE0010839
Top Silver King Size	SE0010369	SE0010593 SE0010660 SE0010754 SE0010790 SE0010839
Gambler Silver King Size	SE0010422	SE0010471 SE0010593 SE0010660 SE0010754 SE0010790 SE0010839

1.3. SCOPE OF REVIEW

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

2. ADMINISTRATIVE REVIEW

Administrative completeness reviews were completed by Ryan Nguy on April 14 and 27, 2014.

The final completeness reviews conclude that the SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate tobacco products are eligible. The OCE reviews dated May 9 and 16, 2014, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products in SE0010365, SE0010369, and SE0010422 are eligible predicate tobacco products because they are grandfathered products (i.e., were commercially marketed as of February 15, 2007). The predicate tobacco product in SE0010366-SE0010368 was determined to be an eligible predicate because it was previously found substantially equivalent by FDA under SE0003199.

The Office of Compliance and Enforcement (OCE) also completed a review to determine whether the new tobacco products are 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 February 4, 2015, and March 25, 2015, 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 disciplines:

4.1. CHEMISTRY

Chemistry reviews were completed by Kimberly Agnew-Heard on May 22, 2014, September 8, 2014, and January 6, 2015.

The final chemistry review concludes that the new tobacco products have different characteristics related to product composition compared to the predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health. The key product composition differences identified in the chemistry reviews are as follows:

(b) (4)

(b) (4)

None of these (b) (4) differences are expected to cause the new tobacco products to raise different questions of public health. However, the applicant submitted (b) (4), and (b) (4) for SE0010365, SE0010369, and SE0010422 by filling the new and predicate tobacco products with (b) (4) in order to address differences in design parameters between the new and corresponding predicate tobacco products. (b) (4) for the new tobacco products in comparison to the corresponding predicate tobacco products. In this case, (b) (4) yields were not necessary because the differences in composition would not be expected to alter (b) (4) yields. Therefore, in this case, 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.

4.2. ENGINEERING

Engineering reviews were completed by Julie Morabito on May 22, 2014, September 16, 2014, and January 8, 2015.

The final engineering review concludes that the new tobacco products have different characteristics related to product design compared to the corresponding predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health. The key design differences identified are as follows:

(b) (4)

(b) (4)
re not expected to cause the new tobacco products to raise different questions of public health. However, the differences in (b) (4) could lead to different constituent yields. Therefore, the applicant determined (b) (4) for the new tobacco products in comparison to the corresponding predicate tobacco products. In this case, (b) (4) yields were not necessary because the differences in design would not be expected to alter (b) (4) yields. Therefore, in this case, the differences in characteristics related to product design between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

4.3. TOXICOLOGY

Toxicology reviews were completed by Brian Erkkila on October 9, 2014, and February 19, 2015.

The final toxicology review concludes that the new tobacco products have different characteristics related to product toxicology compared to the corresponding predicate tobacco products but the differences do not cause the new tobacco products to raise different questions of public health. The key product characteristic differences related to toxicology are as follows:

(b) (4)

The applicant clarified that (b) (4) are present on tipping paper. Because the tipping paper is not burned and (b) (4) does not cause the new tobacco products to raise different questions of public health. The (b) (4) are not being burned and are not likely volatilized from the filter. Therefore, in this case, the differences in characteristics related to product toxicology between the new and corresponding predicate tobacco products do not cause the new tobacco products to raise different questions of public health.

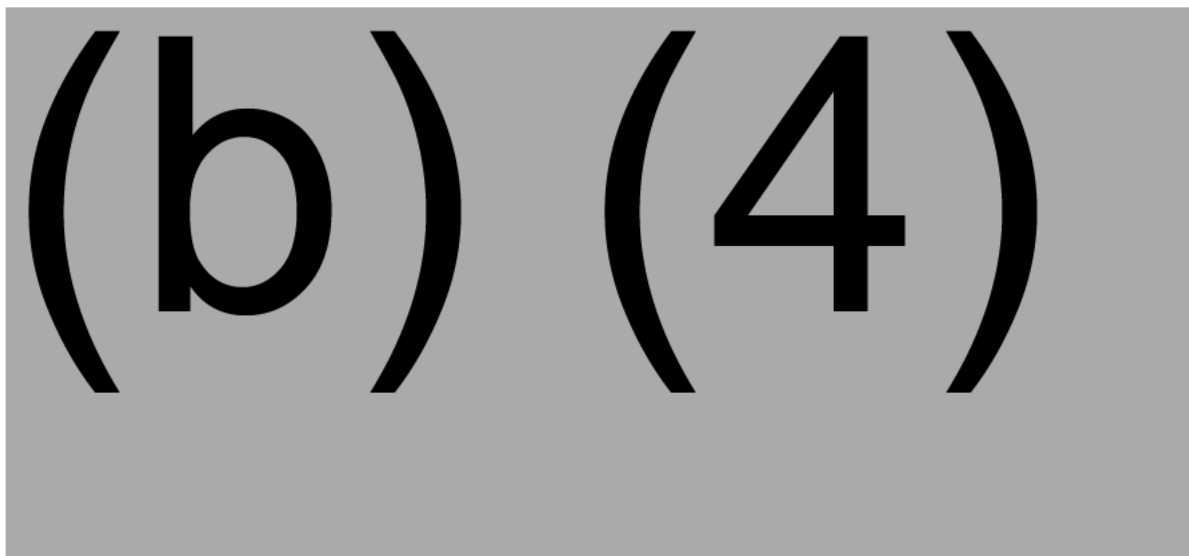
5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on February 25, 2015. The FONSI was supported by an environmental assessment prepared by FDA on February 25, 2015.

6. CONCLUSION AND RECOMMENDATION

SE0010365, SE0010369, and SE0010422

The following are the key differences in characteristics between the new and predicate tobacco products in SE0010365, SE0010369, and SE0010422:



The change in (b) (4) does not cause the new tobacco products to raise different questions of public health because the tipping paper is not burned and the (b) (4) However, these other differences in product characteristics could increase constituent yields. The applicant determined (b) (4)

(b) (4) for the new tobacco products in comparison to the corresponding predicate tobacco products. Therefore, in this case, the differences in characteristics between the new and corresponding predicate products do not cause the new tobacco products to raise different questions of public health.

The predicate tobacco products in SE0010365, SE0010369, and SE0010422 are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007).

SE0010366, SE0010367, and SE0010368

The following are the key differences in characteristics between the new and predicate tobacco products in SE0010366, SE0010367, and SE0010368:

(b) (4)

(b) (4)

The change in (b) (4) does not cause the new tobacco products to raise different questions of public health because the tipping paper is not burned and the (b) (4) are not being burned and are not likely volatilized from the filter. The other differences in product characteristics would be expected to either reduce constituent yields or not affect constituent yields. Therefore, in this case, the differences in characteristics between the new and corresponding predicate products do not cause the new tobacco products to raise different questions of public health.

The predicate tobacco product in SE0010366-SE0010368 was previously determined to be substantially equivalent by FDA under SE0003199. Comparison of the new tobacco products in these SE Reports to the grandfathered product in SE0003199 (Top Gold King Size) reveals the following key differences in characteristics between the new tobacco products and Top Gold King Size, the grandfathered tobacco product (in addition to the differences identified above for the new tobacco products and the predicate tobacco product named by the applicant, Top Gold 100mm):

(b) (4)

The (b) (4) are the same differences in characteristics identified for the new and grandfathered tobacco products in SE0003199. Therefore, these differences do not cause the new tobacco products in SE0010366-SE0010368 to raise different questions of public health. The (b) (4) would be expected to lower HPHC yields.¹ The (b) (4) would also be expected to lower HPHC yields.² Therefore, whether comparing the new tobacco products in SE0010366-SE0010368 to the predicate or grandfathered tobacco products, the new tobacco products do not raise different questions of public health.

1 (b)(4)
(b)(4)

All of the new tobacco products are currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude 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 these reviews and recommend that SE order letters be issued.

FDA has 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 SE0010365, SE0010366, SE0010367, SE0010368, SE0010369, and SE0010422, as identified on the cover page of this review.