

Technical Project Lead (TPL) Review: SE0012635, SE0012638, and SE0012640

SE0012635: Altesse Regular King Size	
Package Type	Box
Package Quantity	100 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	None
Additional Property	Tipping paper from (b) (4) and triacetin from (b) (4)
SE0012638: Gambler Menthol King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping paper from (b) (4) and triacetin from (b) (4)
SE0012640: Gambler Tubecut Menthol King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping paper from (b) (4) and triacetin from (b) (4)
Common Attributes of SE Reports	
Applicant	Republic Tobacco
Report Type	Regular
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Filtered Cigarette Tubes
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2018.02.28 16:35:16 -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: 2018.03.01 08:42:21 -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:

SE0012635: Altesse Regular King Size	
Product Name	Altesse Regular King Size
Package Type	Box
Package Quantity	100 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	None
Additional Property	Tipping paper from (b) (4) and triacetin from (b) (4)
SE0012638: Gambler Menthol King Size	
Product Name	Top Menthol King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping paper from (b) (4) and triacetin from (b) (4)
SE0012640: Gambler Tubecut Menthol King Size	
Product Name	Top Menthol King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Property	Tipping paper from (b) (4) and triacetin from (b) (4)

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant submitted these SE Reports on November 12, 2015. FDA sent Acknowledgement letters on November 23, 2015. On June 27, 2016, FDA held a teleconference with the applicant requesting that Exhibit 14 be resubmitted for SE0012638 and SE0012640. The applicant responded to this request by submitting amendment SE0013469, which FDA received on June 30, 2016 for SE0012638 and SE0012640. FDA issued an Advice/Information Request (A/I) letter to the applicant on August 9, 2016. In response, the applicant submitted amendment SE0013716, which FDA received on September 30, 2016. FDA issued a Preliminary Finding letter on December 23, 2016. The applicant responded with amendment SE0013822, which FDA received on January 18, 2017.

Product Name	SE Report	Amendments
Altesse Regular King Size	SE0012635	SE0013716 SE0013822
Gambler Menthol King Size	SE0012638	SE0013469 SE0013716 SE0013822
Gambler Tubecut Menthol King Size	SE0012640	SE0013469 SE0013716 SE0013822

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

Acceptance reviews were completed by Sarah Webster on November 20, 2015.

The final reviews conclude that the SE Reports are *not* administratively complete; however, during scientific review, all information necessary for completeness and review was identified and provided. Therefore, these 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 grandfathered products (i.e., were commercially marketed as of February 15, 2007). The OCE reviews dated December 22, 2015, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered, and, therefore are eligible predicate tobacco products.

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 April 13, 2017; October 31, 2017; and February 12, 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 disciplines:

4.1. CHEMISTRY

Chemistry reviews were completed by Shixia Feng on August 4, 2016, and December 7, 2016.

The final chemistry review concludes that the new tobacco products have different characteristics compared to the corresponding 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 review identified the following differences related to product composition:

- A change in supplier of triacetin and tipping paper
- Addition of the following ingredients to triacetin:
 - (b) (4)
 - (b) (4)
 - (b) (4)
- Removal of the following ingredients from triacetin:
 - (b) (4)
 - (b) (4)
 - (b) (4)
- An increase in the following tipping paper ingredients in SE0012638 and SE0012640:
 - (b) (4) increase in (b) (4)
 - (b) (4) increase in (b) (4)
 - (b) (4) increase in (b) (4)
- The following changes in tipping paper ingredients in the new tobacco product in SE0012635:
 - (b) (4) decrease in (b) (4)
 - Removal of (b) (4)
 - (b) (4) decrease in (b) (4)
 - Addition of (b) (4)
 - (b) (4) increase in (b) (4)
- Slight modifications to the inks on the packaging (box)

The quantity of triacetin in the new tobacco products is identical to that in the corresponding predicate tobacco products; however, there are slight differences in the triacetin processing ingredients due to different suppliers. Triacetin is a plasticizer that is applied to the filter, a portion of the cigarette that is not combusted. The applicant provided test data for filter density and filter pressure drop, which demonstrate that the changes in the processing ingredients of the triacetin do not cause the new tobacco products to raise different questions of public health. Because tipping paper is not intended to undergo combustion during smoking and the concentrations of these ingredients are relatively small, it is not expected that the changes in

tipping paper ingredients will cause the new tobacco products to raise different questions of public health. The changes to the container closure system (modification of inks) only affect the package design on the outside of the box (i.e., labeling) and are not expected to impact stability of the products. 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 from a chemistry perspective.

4.2. ENGINEERING

Engineering reviews were completed by Komal Ahuja on July 29, 2016, and by Jim Melchiors on November 22, 2016.

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 review identified the following differences related to product design:

- A change in supplier of triacetin and tipping paper
- 2% increase in tipping paper length (0.5 mm)
- 1% decrease in total tube mass

The final engineering review concludes that no notable design parameter differences exist between the new and corresponding predicate tobacco products. The applicant provided all of the target specifications, upper and lower range limits, and test data for the applicable design parameters. The tipping paper in the new tobacco products is 0.5 mm longer than that in the corresponding predicate tobacco products. This increases the amount of tipping paper in the new tobacco products by 0.177 mg (less than 1/10 of 1% of the total tube mass of 199 mg, except for SE0012635, which is decreased by 1.573 mg). This change in tipping paper does not increase the overall length of the cigarette, and because tipping paper is not combusted during consumption, the change in tipping paper does not cause the new tobacco products to raise different questions of public health. 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 from an engineering perspective.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on February 28, 2018. The FONSI was supported by an environmental assessment prepared by FDA on February 28, 2018.

6. CONCLUSION AND RECOMMENDATION

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

- Tipping paper and plasticizer from different suppliers
- 2% increase in tipping paper length (0.5 mm)
- 1% decrease in total tube mass
- Addition of the following ingredients to triacetin:
 - (b) (4)
 - (b) (4)
 - (b) (4)
- Removal of the following ingredients from triacetin:
 - (b) (4)
 - (b) (4)
 - (b) (4)
- An increase in the following tipping paper ingredients in SE0012638 and SE0012640:
 - (b) (4) increase in (b) (4)
 - (b) (4) increase in (b) (4)
 - (b) (4) increase in (b) (4)
- The following changes in tipping paper ingredients in the new tobacco product in SE0012635:
 - (b) (4) decrease in (b) (4)
 - Removal of (b) (4)
 - (b) (4) decrease in (b) (4)
 - Addition of (b) (4)
 - (b) (4) increase in (b) (4)
- Slight modifications to the inks on the packaging (box)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The applicant is changing suppliers for triacetin and tipping paper and there are minor changes to these ingredients as a result. The quantity of triacetin in the new tobacco products is identical to that in the corresponding predicate tobacco products; however, there are slight differences in the processing ingredients. The applicant provided test data for filter density and filter pressure drop, which demonstrate that the changes to triacetin¹ do not cause the new tobacco products to raise different questions of public health. Despite increases in some tipping paper ingredients, the changes are at low levels, which are not expected to increase HPHCs. Additionally, since tipping paper is not combusted in the process of cigarette consumption, it is unlikely that HPHCs will increase with these ingredient modifications. The slight increase in tipping paper length for the new tobacco products does not cause the new tobacco products to raise different questions of public health since it does not increase the overall cigarette length and the tipping paper is not combusted during cigarette consumption. 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.

¹ Triacetin is a component of the cigarette filter.

The predicate tobacco products meet statutory requirements because it was determined that they are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007).

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 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 SE0012635, SE0012638, and SE0012640, as identified on the cover page of this review.