FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0013338 - SE0013340

SE0013338: Gambler Tubecut Regular King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	0%
Characterizing Flavor	None
SE0013339: Gambler Regular King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	0%
Characterizing Flavor	None
SE0013340: Zig-Zag Original King Size	
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	0%
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 a Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2017.11.21 12:15:44 -05'00'

For Matthew J. Walters, Ph.D., MPH
CDR, U.S. Public Health Service
Deputy 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: 2017.11.21 13:23:45 -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:

SE0013338: Gambler Tubecut Regular King Size	
Product Name	Gambler Regular King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	0%
Characterizing Flavor	None
SE0013339: Gambler Regular King Size	
Product Name	Gambler Regular King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	0%
Characterizing Flavor	None
SE0013340: Zig-Zag Original King Size	
Product Name	Gambler Regular King Size
Package Type	Box
Package Quantity	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	0%
Characterizing Flavor	None

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On April 26, 2016, FDA received three SE Reports from Republic Tobacco, LP. FDA issued an Acknowledgment letter to the applicant on May 16, 2016. FDA issued an Advice and Information letter on July 7, 2016. The applicant submitted a response (SE0013675) on August 31, 2016. FDA issued a Preliminary Finding (Pfind) letter on November 2, 2016. The applicant submitted a response (SE0013754) on November 22, 2016. FDA issued a Pfind letter on August 2, 2017. The applicant submitted a response (SE0014254) on August 23, 2017.

Product Name	SE Report	Amendments
Gambler Tubecut Regular King Size	SE0013338	SE0013675 SE0013754 SE0014254

Product Name	SE Report	Amendments
Gambler Regular King Size	SE0013339	SE0013675 SE0013754 SE0014254
Zig-Zag Original King Size	SE0013340	SE0013675 SE0013754 SE0014254

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

The acceptance reviews were completed by Sarah Webster on May 16, 2016. The 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 grandfathered products (i.e., were commercially marketed as of February 15, 2007). The OCE review dated October 25, 2016, concludes 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), (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated October 31, 2017 concludes that the new tobacco products are in compliance with the FD&C Act.

4. SCIENTIFIC REVIEW

Scientific reviews[1] were completed by the Office of Science (OS) for the following disciplines:

4.1. CHEMISTRY

Chemistry reviews were completed by Jeffrey Ammann on June 17, 2016, and October 26, 2016.

The final chemistry review concludes that the new tobacco products have different characteristics compared to the predicate tobacco products but the differences do not cause the

[1] Because there are only minor differences in non-combusted components, the only scientific reviews needed were chemistry and engineering.

new tobacco products to raise different questions of public health from a chemistry perspective. The review identified the following differences:

- Change in the tipping paper and tipping adhesive between the new products compared to the predicate product.
- Change in the coloring materials in the packaging material between the new products compared to the predicate product (SE0013338 and SE0013340).

The applicant changed the tipping paper and the adhesive used to secure the tipping paper which had minor differences in the ingredients between these two components. In addition, the change in the tipping paper and adhesive are not expected to effect HPHC yields and were not needed for these SE Reports to determine substantial equivalence. Also, the applicant changed the packaging materials used between the new and predicate tobacco products. These changes in the tipping paper and adhesive are minor and are not expected to alter the product's performance or change the levels of HPHCs. 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 related to product composition.

4.2. ENGINEERING

Engineering reviews were completed by Komal Singh on June 30, 2016, by Samantha Spindel on October 26, 2016, and by Tiffany Petty on December 21, 2016.

The final engineering 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 an engineering perspective. The review identified the following differences:

- Change in tipping paper;
- Change in tipping paper adhesive;
- Decrease in tipping paper length (4%); and
- Decrease in filtered tube mass (1%).

The applicant changed the tipping paper and the adhesive used to secure the tipping paper as well as decreased the tipping paper length and the filtered tube mass between the new and predicate tobacco products. These changes are minor differences and are not expected to alter the product performance (e.g. increased HPHC yields). 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 November 21, 2017. The FONSI was supported by an environmental assessment prepared by FDA on November 21, 2017.

6. CONCLUSION AND RECOMMENDATION

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

- Change in tipping paper
- Change in the tipping paper adhesive
- Decrease in tipping paper length (4%)
- Decrease in filtered tube mass (1%)

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The changes in tipping paper and the tipping paper adhesives used are minimal and not expected to alter HPHC yields. In addition, the slight decrease in the tipping paper length and filtered tube mass are minor and not expected to alter the performance of the product. These changes are minor in the context of product composition and design. Therefore, 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 meet statutory requirements because 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 differences do not cause the new tobacco products to 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 SE0013338, SE0013339 and SE0013340 as identified on the cover page of this review.