

Technical Project Lead (TPL) Review: SE0015680

SE0015680: Altesse Regular King Size	
Package Type	Box
Package Quantity	250 tubes
Characterizing Flavor	None
Length	84 mm
Diameter	8.2 mm
Ventilation	None
Attributes of SE Report	
Applicant	Republic Tobacco, LP
Report Type	Regular
Product Category	Roll-Your-Own Tobacco Products
Product Sub-Category	Filtered Cigarette Tube
Cross-Referenced Submissions	
SE0015680	(b) (4)
Recommendation	
Issue Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Charles Feng -S
Date: 2020.04.28 10:49:04 -04'00'

Charles Feng, Ph.D.
Chemistry Branch Chief
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: 2020.04.28 10:59:35 -04'00'

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

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCT

The applicant submitted the following predicate tobacco product:

SE0015680: Altesse Regular King Size	
Product Name	Gambler Regular King Size
Package Type	Box
Package Quantity	200 tubes
Characterizing Flavor	None
Length	84 mm
Diameter	8.2mm
Ventilation	None

The predicate tobacco product is a roll-your-own (RYO) filtered cigarette tube manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On February 4, 2020, FDA received a Substantially Equivalent (SE) Report (SE0015680) from Republic Tobacco, LP. FDA issued an Acceptance letter for this SE Report on February 11, 2020. In a teleconference on February 19, 2020, FDA requested the applicant provide information for the Office of Compliance and Enforcement’s (OCE) evaluation of the predicate tobacco product. On February 21, 2020, FDA received an amendment (SE0015724) containing the requested information.

Product Name	SE Report	Amendment
Altesse Regular King Size	SE0015680	SE0015724

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific review completed for this SE Report.

2. REGULATORY REVIEW

A regulatory review was completed by Donna Cheung on February 11, 2020. The review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

OCE completed a review to determine whether the applicant established that the predicate tobacco product 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 March 11, 2020,

concludes that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco product is grandfathered and, therefore, is an eligible predicate tobacco product.

OCE also completed a review to determine whether the new tobacco product is 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 April 9, 2020, concludes that the new tobacco product is 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

A chemistry review was completed by Delauren Mccauley on March 19, 2020¹.

The chemistry review concludes that the new tobacco product has different characteristics related to product chemistry compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- Decrease in complex ingredients: tipping paper (↓ 6%), glue seam/filter (↓ 50%), (b) (4) (↓ 6%), glue filter hot melt (↓ 68%), glue filter (↓ 43%), ink (↓ 50%), tipping glue (↓ 30%)
- Increase in (b) (4) (↑16%) in the filter
- Addition of (b) (4) mg/tube) in the tipping glue

There are differences in ingredient quantities between the new and predicate tobacco products (i.e., tipping paper (↓6%), glue seam/filter (↓50%), (b) (4) (↓6%), glue filter hot melt (↓68%), glue filter (↓43%), ink (↓50%), tipping glue (↓30%), and (b) (4) (↑16%). Although there is a 16% increase in (b) (4) (a plasticizer in filter) in the new tobacco product compared to the predicate tobacco product, this ingredient is not combusted in the finished product when used as intended, therefore, is not expected to increase HPHCs. The decreases in other ingredients are also not expected to increase HPHCs. Therefore, from a chemistry perspective, the differences in ingredients between the new and predicate tobacco do not cause the new tobacco product to raise different questions of public health.

The applicant provided mainstream smoke yields for tar, nicotine, and carbon monoxide (TNCO) in the new and predicate tobacco products, under ISO and CI smoking regimens. TNCO yields were evaluated using a two one-sided t-test (TOST) equivalence test for mean values between the new and predicate tobacco products. Mainstream smoke yields included a 5-8% difference between the new and predicate tobacco products, which were analytically equivalent, except for tar (↓8%). Therefore, tar is deferred to toxicology for further evaluation. The engineering deferred to chemistry for the evaluation of TNCO and B[a]P

¹ An addendum review was completed on April 27, 2020, to reference a review of the tobacco product master file (b) (4) in support of the chemistry review.

yields. However, B[a]P yield is expected to decrease based on the engineering review, hence, B[a]P data is not needed for chemistry. Therefore, the design changes do not negatively impact the HPHC yields.

Therefore, the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health from a chemistry perspective.

4.2. ENGINEERING

An engineering review was completed by Robert Meyer on March 18, 2020.

The engineering review concludes that the new tobacco product has different characteristics related to product engineering compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- 6% increase in filter pressure drop
- 5% decrease in denier per filament

The most notable differences between the new and predicate products are the 6% higher filter pressure drop, and 5% less denier per filament in the new product; in combination it is likely the filter in the new product restricts more tar and nicotine. Engineering defers the filter pressure drop, and filter denier per filament differences to chemistry for the evaluation of the yields of tar, nicotine, and B[a]P of the new and predicate products.

Therefore, the differences in characteristics between the new and predicate tobacco products do not cause the new tobacco product to raise different questions of public health from an engineering perspective.

4.3. TOXICOLOGY

A toxicology review was completed by Kimberly Stratford on March 19, 2020.

The toxicology review concludes that the new tobacco product has different characteristics related to product toxicology compared to the predicate tobacco product, but the differences do not cause the new tobacco product to raise different questions of public health. The review identified the following differences:

- Increased ingredients in the glue seam/filter: (b) (4) (↑1.24%; by (b) (4) mg/injector tube)
- Added and increased ingredients to the plugwrap: (b) (4) mg/injector tube), (b) (4) mg/injector tube), (b) (4) mg/injector tube) (↑100%; (b) (4) mg/injector tube)
- Added ingredients to the glue filter: (b) (4) mg/injector tube)
- Added ingredients to the tipping glue: (b) (4) mg/injector tube), (b) (4) mg/injector tube), (b) (4) mg/injector tube)

- mg/injector tube) and (b) (4) mg/injector tube)
- Added ingredients to (b) (4) ↑16% (b) (4) mg/injector tube): (b) (4) mg/injector tube), (b) (4) mg/injector tube)
- Added or increased ingredients to ink (rod print): (b) (4) mg/ injector tube), (b) (4) mg/injector tube), (b) (4) mg/injector tube), (b) (4) (↑200%; (b) (4) mg/injector tube), (b) (4) (↑1900%; (b) (4) mg/injector tube)

There were ingredient increases in the unburned components of the new tobacco product compared to the predicate tobacco product. (b) (4) is a plasticizer in the filter and increased 16% (b) (4) mg/injector tube). There were also added or increased ingredients in the glue seam/filter, plugwrap, glue filter, tipping glue; but they are not expected to be combusted, volatilized, or released during cigarette consumption, thus, consumer exposure to these ingredients while smoking is expected to be minimal. Therefore, changes in these ingredients are not likely to cause the new tobacco product to raise different questions of public health from a toxicological perspective.

The applicant did not provide the location for the ink (rod print) used in the new tobacco product. However, the total amount of ink was decreased by 50% in the new product compared to the predicate product. The applicant provided tar and CO data for the new and predicate tobacco products using an identical RYO tobacco blend. The yields of tar and CO in the mainstream smoke were decreased or slightly increased but analytically equivalent in the new tobacco product compared to the predicate product. Therefore, the increased and added ingredients in ink do not raise different questions of public health from a toxicological perspective.

Therefore, the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health from a toxicology perspective.

5. ENVIRONMENTAL DECISION

An environmental review was conducted by Dilip Venugopal on March 17, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 15, 2020. The FONSI was supported by an environmental assessment prepared by FDA on April 15, 2020.

6. CONCLUSION AND RECOMMENDATION

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

- Decrease in complex ingredients: tipping paper (↓ 6%), glue seam/filter (↓ 50%), (b) (4) (b) (4) (↓ 6%), glue filter hot melt (↓ 68%), glue filter (↓ 43%), ink (↓ 50%), tipping glue (↓ 30%)
- Increase in (b) (4) (↑16%) in the filter
- Increased ingredients in the glue seam/filter: (b) (4) (↑1.24%; by (b) (4) mg/injector tube)

- Added and increased ingredients to the plugwrap: (b) (4) mg/injector tube), (b) (4) mg/injector tube), (b) (4) mg/injector tube), (b) (4) (↑100%; (b) (4) mg/injector tube)
- Added ingredients to the glue filter: (b) (4) mg/injector tube)
- Added ingredients to the tipping glue: (b) (4) mg/injector tube), (b) (4) mg/injector tube) and (b) (4) mg/injector tube)
- Added or increased ingredients to ink (rod print): (b) (4) mg/ injector tube), (b) (4) mg/injector tube), (b) (4) mg/injector tube), (b) (4) mg/injector tube), (b) (4) (↑200%; (b) (4) mg/injector tube), (b) (4) (↑1900%; (b) (4) mg/injector tube)
- 6% increase in filter pressure drop
- 5% decrease in denier per filament

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. There were many ingredient changes in the unburned components of the new tobacco product compared to the predicate tobacco product. For example, (b) (4) a plasticizer in the filter, increased by 16%. There were also added or increased ingredients in the filter seam glue, plugwrap, and tipping glue; but they are not expected to be combusted, volatilized, or released during cigarette consumption, thus, consumer exposure to these ingredients while smoking is expected to be minimal. The changes in design parameters (filter pressure drop and denier per filament) are expected to decrease TNCO yields. The applicant provided TNCO yields under both ISO and CI regimens, which indicated a significant decrease in tar yield and analytically equivalent nicotine and CO yields. There was a 50% decrease in the total quantity of ink (rod print) ingredients, although there were some small increases in several individual ingredients comprising the ink. However, due to the decrease in the total ink quantity and the decrease in tar yield and the analytically equivalent CO yields, the increased and added individual ink ingredients do not raise concerns from a toxicological perspective. Finally, there was a change in product quantity from 200 tubes to 250 tubes per package. However, based on the currently available scientific evidence and CTP's experience in reviewing SE Reports, OS has developed a memo which concluded that, at this time, changes in tobacco product quantity does not cause new tobacco products to raise different questions of public health.² Therefore, the differences in characteristics between the new and predicate tobacco product do not cause the new tobacco product to raise different questions of public health.

The predicate tobacco product meets statutory requirements because it was determined that it is a grandfathered tobacco product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

The new tobacco product is currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude that the differences between the new and predicate tobacco product are such that the new tobacco product does not raise different questions of public health. I concur with these reviews and recommend that an SE order letter be issued.

FDA examined the environmental effects of finding this new tobacco product substantially

² Internal memorandum: Product quantity changes in Substantial Equivalence Reports (SE Reports) for statutorily regulated tobacco products (December 7, 2017).

equivalent and made a finding of no significant impact.

An SE order letter should be issued for the new tobacco product in SE0015680, as identified on the cover page of this review.