Technical Project Lead (TPL) Review : SE0002190 and SE0002191, SE0014483-SE0014486

SE0002190: Old Gold Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	80 mm
Diameter	7.9 mm
Ventilation	18%
Characterizing Flavor	None
Additional Properties	LIP Cigarette Paper 1
SE0002191: Old Gold Kings	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	20%
Characterizing Flavor	None
Additional Properties	LIP Cigarette Paper 1
SE0014483: Old Gold Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	80 mm
Diameter	7.9 mm
Ventilation	18%
Characterizing Flavor	None
Additional Properties	LIP Cigarette Paper 2
SE0014484: Old Gold Box	
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	80 mm
Diameter	7.9 mm
Ventilation	18%
Characterizing Flavor	None
Additional Properties	LIP Cigarette Paper 3

SE0014485: Old Gold Kings	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	20%
Characterizing Flavor	None
Additional Properties	LIP Cigarette Paper 2
SE0014486: Old Gold Kings	
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	20%
Characterizing Flavor	None
Additional Properties	LIP Cigarette Paper 3
Common Attributes of SE Reports	
Applicant	R.J. Reynolds Tobacco Company
Report Type	Provisional
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Kenneth Taylor -S
Date: 2018.06.05 08:46:42 -04'00'

Kenneth M. Taylor, 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: 2018.06.05 09:47:30 -04'00'

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

TABLE OF CONTENTS

1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0002190: Old Gold Box	
Product Name	Old Gold Kings Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	80 mm
Diameter	7.9 mm
Ventilation	None
Characterizing Flavor	None
SE0002191: Old Gold Kings	
Product Name	Old Gold Kings
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	None
Characterizing Flavor	None
SE0014483: Old Gold Box	
Product Name	Old Gold Kings Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	80 mm
Diameter	7.9 mm
Ventilation	None
Characterizing Flavor	None
SE00014484: Old Gold Box	
Product Name	Old Gold Kings Box
Package Type	Hard Pack
Package Quantity	20 cigarettes
Length	80 mm
Diameter	7.9 mm
Ventilation	None
Characterizing Flavor	None

SE0014485: Old Gold Kings	
Product Name	Old Gold Kings
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	None
Characterizing Flavor	None
SE0014486: Old Gold Kings	
Product Name	Old Gold Kings
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	None
Characterizing Flavor	None

The predicate tobacco products are combusted filtered cigarettes manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant originally submitted two SE Reports (SE0002190 and SE0002191) on March 22, 2011.[1] FDA issued Acknowledgement letters on August 23, 2011. The applicant submitted amendments SE0003826 and SE0003827 on October 28, 2011. FDA issued an Advice and Information Request Letter (A/I Letter) on January 4, 2013. In response, the applicant submitted amendments SE0006998 and SE0006999 on February 1, 2013. In addition, the applicant submitted another amendment SE0010173 on February 10, 2014. A Notification letter was issued to the applicant on December 11, 2015 indicating that scientific review would begin on January 25, 2016. The applicant responded to the Notification letter with amendments SE0012801 and SE0012802 on January 22, 2016. The applicant submitted an additional amendment (SE0013009) on March 18, 2016 correcting Grandfathered STN information for SE0002190 predicate tobacco product. An A/I Letter was issued to the applicant on June 6, 2016. The applicant responded to this letter with amendment SE0013557 on August 5, 2016. A Preliminary Finding letter was issued to the applicant on April 18, 2017. The applicant responded to the letter with amendment SE0014094 on May 18, 2017. In the amendments (SE0013557 and SE0014094) the applicant identified three unique versions of the new tobacco products, based upon the use of three alternate cigarette paper materials. Therefore, FDA

[1] FDA acknowledged the transfer of ownership from Lorillard Tobacco Company to R.J. Reynolds Tobacco Company on October 1, 2015.

established four additional STNs (SE0014483-SE0014486). For these additional STNs, FDA issued Acknowledgment letters on February 8, 2018.

Product Name	SE Report	Amendments
Old Gold Box	SE0002190	SE0003826 SE0006998 SE0010173 SE0012801 SE0013009 SE0013557 SE0014094
Old Gold Kings	SE0002191	SE0003827 SE0006999 SE0010173 SE0012802 SE0013557 SE0014094

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

Regulatory reviews were completed by Theodore Riley on August 23, 2011, Rosanna Beltre on January 4, 2013, Angela Brown on March 11, 2014, Ryan Nguy on August 12, 2016, and Jennifer Schmitz on May 24, 2017 and February 8, 2018.

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 in the United States other than exclusively in test markets as of February 15, 2007). The OCE reviews dated March 4, 2016 and March 2, 2018 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 did not complete 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) because the new tobacco products subject to this[ese] SE Report(s) are provisional.

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 Melissa McCulloch on May 12, 2016, and October 13, 2016, and by An Vu on July 13, 2017.

The final chemistry review concludes that the new tobacco products have different characteristics related to product chemistry 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:

- The new tobacco products contain low ignition propensity (LIP) cigarette papers, whereas the predicate tobacco products do not
- The use of interchangeable cigarette papers in the new tobacco products with different ingredients from the corresponding predicate tobacco products
    - SE0002190 is identical to SE0014483 and SE0014484 with the exception that each of the cigarette papers used contain different ingredients
    - SE0002191 is identical to SE0014485 and SE0014486 with the exception that each of of the cigarette papers used contain different ingredients

The applicant provided TNCO data for the new tobacco products with each of the three new tobacco product papers and the predicate tobacco product paper. The TNCO yields do not show any significant differences between each new tobacco product and the predicate tobacco product under both ISO and Canadian Intense smoking regimens.

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 Michael Morschauser on April 25, 2016; November 8, 2016; and July 12, 2017.

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

The new tobacco products have the following key differences in product design compared to the corresponding predicate tobacco products:

- Increases in filter ventilation and a corresponding decrease in cigarette draw resistance
- Use of interchangeable cigarette papers in the new products with different ingredients from the corresponding predicate products
    - SE0002190 is identical to SE0014483 and SE0014484 with the exception that each of the cigarette papers used contain different ingredients
    - SE0002191 is identical to SE0014485 and SE0014486 with the exception that each of the cigarette papers used contain different ingredients

Both the new and predicate tobacco products initially contained multiple alternate materials for seven components, including cigarette paper, filter tow, plug wrap, tipping paper, and adhesives. In response to the Advice and Information Request letter, the applicant withdrew all alternate materials for the predicate tobacco product, and eliminated all alternate materials for the new tobacco product with the exception of three cigarette papers.

The new tobacco products are ventilated, while the predicate tobacco products are not. This resulted in a decrease in cigarette draw resistance for the new tobacco products. Since the addition of ventilation reduces the concentration of smoke constituents, this change does not cause the new tobacco products to raise different questions of public health. The chemistry review shows that the three different cigarette papers do not cause the new tobacco products to raise different questions of public health.

Therefore, 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 Zheng Tu on May 13, 2016, and April 3, 2017.

The final toxicology review concludes that the new tobacco products have different characteristics related to product toxicity compared to the predicate tobacco products and that the SE Reports lack adequate evidence to

demonstrate that the differences do not cause the new tobacco products to raise different questions of public health with respect to product toxicology. The review identifies the following deficiencies that have not been adequately resolved:

1. Both of the new tobacco products use interchangeable materials for cigarette papers, plug wraps, filter tows, side seam adhesives, tipping adhesives, and tipping papers in both the new and predicate products. The applicant manufactured only 3 new products and 1 predicate product with specific combinations of materials as representatives of the 1,056 possible products to measure the levels of TNCO. Even though, TNCO yields are not significantly different between each new and predicate products tested, three new product combinations and one predicate product combination do not represent all the product combinations outlined in the applicant's responses since the applicant only tested 0.38% products out of the 100% possible products. Scientific evidence is needed to support that the new products containing each interchangeable material do not raise different questions of public health as compared to their respective predicate products.

2. Both of the new tobacco products provide updated ingredient information for cigarette papers, plug wraps, tipping papers, filter tows, tipping adhesives, filter anchor line adhesives, monogram ink and side seam adhesives. The information includes the composition of the interchangeable materials. However, the weight percentage of components of most cigarette papers, filter tow materials, tipping materials, plug wraps, and side seam adhesives do not equal to 100%. Clarification of this data is needed.

Therefore, the review concludes that there was inadequate information from a toxicology perspective to determine that 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. However, the toxicology review also indicates that the use of interchangeable ingredients and the weight percentage deficiencies are the same as those also addressed in the engineering and chemistry reviews, respectively[2]. The third engineering review explains the applicant withdrew all alternate materials for the predicate product and eliminated all multiple materials for the new products with the exception of three cigarette papers. Similarly, the third chemistry review concludes that the use of all cigarette materials and components do not raise concerns because of identical or nearly identical material formulations and amounts, or non-combusted materials; moreover, TNCO results for the new and corresponding predicate tobacco products showed no significant difference. Therefore, the toxicology conclusion regardinginsufficient information is adequately addressed by the chemistry and engineering reviews and is not needed for a determination regarding substantial equivalence.

[2] These deficiencies were conveyed in the PFIND letter following the second review cycle by chemistry and engineering disciplines, and were evaluated in a third review cycle.

5. ENVIRONMENTAL DECISION

Under 21 CFR 25.35(a), issuance of SE orders under section 910(a) of the FD&C Act for these provisional SE Reports is categorically excluded and, therefore, normally does not require the preparation of an environmental assessment (EA) or an environmental impact statement. FDA has considered whether there are extraordinary circumstances that would require the preparation of an EA and has determined that none exist.

6. CONCLUSION AND RECOMMENDATION

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

- The use of low ignition propensity (LIP cigarette papers
- The use of interchangeable types of cigarette papers in the new tobacco products each with different ingredients from the corresponding predicate products
- Addition of filter ventilation and a corresponding decrease in cigarette draw resistance

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco products to raise different questions of public health. The addition of ventilated filters in the new tobacco products, which reduces cigarette draw resistance, reduces the concentration of smoke constituents.
The applicant provides TNCO data from intense and non-intense smoking regimens for the new tobacco products fabricated with each of the three interchangeable LIP cigarette papers. The TNCO yields from each of the new tobacco products are either less than the yields measured for the corresponding predicate tobacco products or within analytical variability. 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 it was determined that they are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

All of the scientific reviews except toxicology 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. As stated above, the issues raises by the toxicology review are addressed in the chemistry and engineering reviews; accordingly, I find that the toxicology conclusion to be moot. I concur with the chemistry and engineering reviews and recommend that SE order letters be issued.

Because the proposed action is issuing SE orders for these provisional SE Reports, it is a class of action that is categorically excluded under 21 CFR 25.35(a). FDA has considered whether there are extraordinary circumstances that would require the preparation of an environmental assessment and has determined that none exist. Therefore, the proposed action does not require preparation of an environmental assessment or an environmental impact statement.

SE order letters should be issued for the new tobacco products in SE0002190 and SE0002191, and SE0014483-SE0014486, as identified on the cover page of this review.