FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: SE0015581

SE0015581: Pall Mall Orange Filter Box	
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	58%
Characterizing Flavor	None
Attributes of SE Report	
Applicant	R.J. Reynolds Tobacco Company
Report Type	Regular
Product Category	Cigarette
Product Sub-Category	Combusted filtered
Recommendation	
Issue Substantially Equivalent (SE) order.	

Technical Project Lead (TPL):

Digitally signed by Gloria J. Kulesa -S
Date: 2020.02.28 14:20:21 -05'00'

Gloria Kulesa
Engineering 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: 2020.02.28 16:09:10 -05'00'

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:

SE0015581: Pall Mall Orange Filter Box	
Product Name	Pall Mall Ultra Light Box
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	58%
Characterizing Flavor	None

The predicate tobacco product is a combusted, filtered cigarette manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On December 3, 2019, FDA received one SE Report from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. FDA issued an Acceptance letter to the applicant on December 10, 2019.

Product Name	SE Report	Amendments
Pall Mall Orange Filter Box	SE0015581	None

1.3. SCOPE OF REVIEW

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

2. REGULATORY REVIEW

A regulatory review was completed by Tacheka Bailey on December 10, 2019. The review concludes that the SE Report is administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (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 January 8, 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 February 10, 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 Abdur-Rafay Shareef on February 7, 2020.

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:

- An alternative fire standard compliant (FSC) cigarette paper
- An alternative tipping paper
- Lower [redacted] (↓ 8%), and removed [redacted]
- Higher [redacted] (↑ 11%), [redacted] (↑ 3%), and [redacted] (↑ 4%)

In SE0015581 the applicant indicated that the new and predicate tobacco products contained nearly identical total tobacco, [redacted] mg. versus [redacted] mg., respectively. The individual blend components were modified: [redacted] was removed, and [redacted] was ↓ 8% in the new tobacco product compared to the predicate tobacco product. Higher levels of [redacted] (↑ 11%), [redacted] (↑ 3%), and [redacted] (↑ 4%) tobacco were reported in SE0015581 for the new tobacco product. Furthermore, existing individual ingredient inclusion levels (↑ 0-4%) were modified in the new tobacco product compared to the predicate tobacco product. Finally, an alternative FSC cigarette paper and alternative tipping papers were reported. The engineering reviewer identified HPHCs of concern based on design changes to the cigarette paper band porosity, band width, and band spacing. The applicant submitted appropriate TNCO and HPHC yields under both ISO and CI regimens in support of design and compositional changes indicated in SE0015581. Finally, all HPHC and TNCO yields submitted in SE0015581 were analytically equivalent, and therefore no additional information is required in the chemistry review. Thus, from a chemistry perspective, the new tobacco product does not raise different questions of public health.

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 James Melchiors on January 10, 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:

- The cigarette paper band width that is 17% greater
- The cigarette paper band spacing that is 15% lower
- The measured values provided for the cigarette paper band porosity in lieu of specifications that are lower than the lower range limit for the predicate tobacco product
- The filter tow with a total denier that is 13% greater
- The filter tow with a denier per filament that is 17% lower

The new tobacco product uses a different cigarette paper than the predicate tobacco product. Specifically, the design parameters cigarette paper band porosity, band width, and band spacing are different and these differences may affect harmful and potentially harmful constituent (HPHC) yields including TNCO, 1,3-butadiene, and acrylonitrile yields. Therefore, engineering defers these differences to chemistry. The new tobacco product uses a filter tow with a total denier of (b)(4) g/9000m and a denier per filament (DPF) of (b)(4) DPF, while the predicate tobacco product uses a filter tow with a total denier of (b)(4) g/9000m and a denier per filament of (b)(4) DPF. This represents an increase of 13% in the total denier and a decrease of 17% in the denier per filament. Both an increase in total denier and a decrease in denier per filament would be expected to improve the performance of the filter. While the new tobacco product also uses a different filter tow than the predicate tobacco product, the evaluation determined that this different tow would not cause the new tobacco product to raise different questions of public health from an engineering 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 an engineering perspective.

4.3. TOXICOLOGY

A toxicology review was completed by Kristen Wurcel on January 23, 2020.

The toxicology review concludes that the new tobacco product has different characteristics related to 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 levels of (b) (4) mg/cigarette or ↑4%), (b) (4) mg/cigarette or ↑1%), (b) (4) (↑(b) (4) mg/cigarette or ↑4%), (b) (4) (↑(b) (4) mg/cigarette or ↑4%), and (b) (4) (↑(b) (4) mg/cigarette or ↑4%)
- The addition of (b) (4) ((b) (4) mg/cigarette), (b) (4) mg/cigarette), and (b) (4) mg/cigarette)
- A decrease in the total (b) (4) content

For the ingredients added to the tobacco and the cigarette paper, data in SE0015581 demonstrate analytical equivalence in levels of HPHCs (i.e., CO, acetaldehyde, acrolein, acrylonitrile, benzene, B[a]P, 1,3-butadiene, formaldehyde). Therefore, the increased ingredients, at the levels in the new product compared to the predicate product, do not cause the new product to raise different questions of public health from a toxicology perspective. For the decrease in the total (b) (4) content, data in SE0015581 demonstrate analytical equivalence in TNCO and puff count. Therefore, the decreased (b) (4) content in the new product compared to the predicate product does not raise different questions of public health from a toxicology 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 completed by Shannon Hanna on January 16, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on January 24, 2020. The FONSI was supported by an environmental assessment prepared by FDA on January 24, 2020.

6. CONCLUSION AND RECOMMENDATION

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

- An alternative fire standard compliant (FSC) cigarette paper
- An alternative tipping paper
- Lower (b) (4) (↓ 8%), and removed (b) (4)
- Higher (b) (4) (↑ 11%), (b) (4) (↑ 3%), and (b) (4) (↑ 4%)
- The cigarette paper band width that is 17% greater
- The cigarette paper band spacing that is 15% lower
- The filter tow with a total denier that is 13% greater
- The filter tow with a denier per filament that is 17% lower
- Increased levels of (b) (4) mg/cigarette or ↑4%), (b) (4) (↑ (b) (4) mg/cigarette or ↑1%), (b) (4) (↑ (b) (4) mg/cigarette or ↑4%), (b) (4) (↑ mg/cigarette or ↑4%), and (b) (4) (↑ (b) (4) mg/cigarette or ↑4%)
- The addition of (b) (4) mg/cigarette), (b) (4) mg/cigarette), and (b) (4) mg/cigarette)
- A decrease in the total (b) (4) content

The applicant has demonstrated that these differences in characteristics do not cause the new tobacco product to raise different questions of public health. Several design parameters changed between the new and predicate tobacco products which may have had an effect on TNCO and HPHC yields. The applicant submitted TNCO and HPHC's under both ISO and CI regimens for the new and

predicate products. These design differences demonstrated analytically equivalent levels of TNCO and HPHCs and therefore, do not cause the new product to raise different questions of public health. Furthermore, the differences in the tobacco blend and ingredients also demonstrated analytically equivalent levels of HPHC's, therefore the differences in characteristics between the new and corresponding predicate tobacco products do you not cause the new tobacco product to raise different questions of public health. 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 equivalent and made a finding of no significant impact.

An SE order letter should be issued for the new tobacco product in SE0015581, as identified on the cover page of this review.